United States of America

Confidence Building Measure Return covering 2017

Convention on the Prohibition of the Development, Production and Stockpiling of
Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on
April 15, 2018

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F		√	1997
G			

Date: April 15, 2018

State Party to the Convention: United States of America

Date of ratification/accession to the Convention: March 26, 1975

National point of contact: Mr. Christopher Park, Department of State

Inquiries may be directed to ISN-BPS-DL@state.gov.

Report of the United States of America to the United Nations Department for Disarmament Affairs

Pursuant to the procedural modalities agreed upon in April 1987 at the "Ad Hoc Meeting of Scientific and Technical Experts for States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," the United States of America submits the following information under Article V of the Convention:

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Confidence Building Measure A, Part 2
Exchanges of information on national biological defence research and development programmes
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List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens page 183

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Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2018

Exchange of data on research centres and laboratories

1. Name(s) of facility.
National Biodefense Analysis and Countermeasures Center (NBACC)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
U.S. Department of Homeland Security Science and Technology Directorate
Operated by Battelle National Biodefense Institute LLC

3. Location and postal address.
8300 Research Plaza, Fort Detrick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Department of Homeland Security (DHS)
U.S. Department of Defense (DOD) - partly
U.S. Department of Justice (DOJ)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL 4 Laboratory 980 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism. (http://bnbi.org/)

The types of agents registered for use at NBACC are BSL-2 toxins, BSL-2 gram positive and gram negative bacterial agents, BSL-2 viral agents, BSL-3 gram positive and gram negative bacterial agents, BSL-3 viral agents, and BSL-4 viral agents.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
U.S. Army Medical Research and Materiel Command

3. Location and postal address.
1425 Porter Street, Fort Detrick, Frederick, Maryland 21702-5011

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Department of Defense (DoD) – Partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL 4 Laboratory 1186 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
USAMRIID conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents include vaccines, drugs, diagnostic capabilities, and various medical management procedures.

Additional information can be found at: http://www.usamriid.army.mil/

Exchange of data on research centres and laboratories

1. **Name(s) of facility.**
   Centers for Disease Control (CDC), Office of Infectious Diseases (OID)
   [Declared in accordance with Form A, Part 2 (iii)]

2. **Responsible public or private organization or company.**
   Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

3. **Location and postal address.**
   1600 Clifton Road N.E., Atlanta, Georgia, 30333

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**
   U.S. Agency for International Development (USAID)
   U.S. Department of Defense (DOD) - partly
   U.S. Department of Health and Human Services (HHS)
   U.S. Department of Homeland Security (DHS)
   U.S. Department of State (DOS)

5. **Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2).**

BSL-4 Laboratory	127 m^2
BSL-4 Laboratory	279 m^2
BSL-4 Laboratory	127 m^2

6. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**
   Activities include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, evaluating vaccines and medical countermeasures, determining the natural history of infectious organisms, assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. Additional information can be found at: http://www.cdc.gov/oid/. Please note, in 2017, 127 square meters of the reported BSL-4 space was utilized as BSL-3 Enhanced (BSL-3E) space, but remained capable of being used as BSL-4 space.

Biodefense activities include those with select agents (the select agents list is available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html).

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility

Integrated Research Facility at Fort Detrick (IRF – Frederick)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company

National Institutes of Health (NIH), Department of Health and Human Services (HHS)
Operated by Battelle Memorial Institute

3. Location and postal address

8200 Research Plaza, Frederick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services (HHS)

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)

BSL 4 Laboratory 1305 m^2

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

The Integrated Research Facility at Fort Detrick in Frederick, Maryland (IRF-Frederick) is a component of the Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The mission of the IRF-Frederick is to manage, coordinate, and facilitate the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research emphasis is placed on elucidating the nature of high consequence pathogens. Additional information can be found at: http://www.niaid.nih.gov/about/organization/dir/irf/Pages/default.aspx.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility

Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company

National Institutes of Health (NIH), Department of Health and Human Services (HHS)

3. Location and postal address

903 South 4th Street, Hamilton, Montana 59840 United States

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services (HHS)

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)

BSL-4 Laboratory	1145 m^2

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The RML mission is to play a leading role in the nation's efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Research at the Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML) is dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Additional information can be found at: https://www.niaid.nih.gov/about/integrated-research-facility .

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility[2]
Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

2. Responsible public or private organization or company
The University of Texas Medical Branch

3. **Location and postal address**
301 University Boulevard, Galveston, Texas 77555

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services (HHS)
State of Texas and the University of Texas Medical Branch
National Institutes of Health (NIH)
U.S. Department of Agriculture (USDA)
Private Foundations
Pharmaceutical and Biotechnology Industries
U.S. Department of Energy (DOE)
U.S. Department of Defense (DOD) - partly
U.S. Department of Homeland Security (DHS)
Centers for Disease Control and Prevention (CDC)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)

BSL-4 Laboratory	186 m^2
BSL-4 Laboratory	1022 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate
The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines.
Additional information can be found at: http://www.utmb.edu/gnl/.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility

The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology

2. Responsible public or private organization or company

Texas Biomedical Research Institute

3. Location and postal address

P.O. Box 760549, San Antonio, Texas 78245-0549

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services (HHS)
Department of Defense (DOD) - partly
Department of Homeland Security (DHS)
Private Sector Companies
Private Donors

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)

BSL 4 Laboratory	114 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

The mission of the Laboratory is to develop vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents. Additional information can be found at:
https://www.txbiomed.org/about/extraordinary-resources/.

Exchange of data on research centres and laboratories

1. Name(s) of facility
Viral Immunology Center - National B Virus Resource Laboratory

2. Responsible public or private organization or company
Georgia State University

3. Location and postal address
P. O. Box 4118, Atlanta, Georgia 30302-4118

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services
Georgia Research Alliance
Immunology Core Support
Elizabeth R. Griffin Research Foundation

* This facility did not operate during calendar year 2017. The financing sources above apply to the financing sources for calendar year 2016, as per the U.S. CBM covering that period. The facility is expected to resume operations in 2018.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL 4 Laboratory 60 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate
The National B Virus Resource Laboratory did not operate during the calendar year of 2017, but is expected to resume operations in 2018. The U.S. BWC CBM covering 2018 will reflect this resumption of activities at this facility. The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. In 2016, the last year of reportable operations at this facility, projects at the National B Virus Resource Laboratory were focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focused on the mechanisms by which virus kills the host and how that process can be circumvented with:

- **Early identification** - research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- **Appropriate antiviral drugs** - researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- **In the future, effective vaccines**.

Additional information can be found at http://www2.gsu.edu/~wwwvir/Research/Index.html

Form A, Part 2 (i)

BWC - Confidence Building Measure

National biological defence research and development programmes - Declaration

United States of America

April 15, 2018

Form A, Part 2 (i)

National biological defence research and development programme: Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes ☒

No ☐

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme

Form A, Part 2 (ii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Description

United States of America

April 15, 2018

Form A, Part 2 (ii)

National biological defence research and development programmes: Overview

The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the *National Strategy for Countering Biological Threats*, this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. These programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of their pathogenicity and other characteristics. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development work, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health needs. Efforts to improve medical product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and to clean up the site of a biological weapons attack have civilian applications that benefit public health services, such as epidemiological disease surveillance and environmental remediation.

To promote the benefits gained by these programs and to ensure that the research is available to the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

For more information on U.S. Government strategies related to biodefense, including biological threat preparedness and response, please consult:

- Management of Domestic Incidents (Homeland Security Presidential Directive 5 [HSPD-5]) and the related National Response Framework;
- Presidential Policy Directive 8: National Preparedness (PPD-8);
- National Strategy for Defense of United States Agriculture and Food (HSPD-9);
- National Biodefense Strategy (HSPD-10/National Security Presidential Directive-33 [NSPD-33]);
- Medical Countermeasures against Weapons of Mass Destruction (HSPD-18);
- Public Health and Medical Preparedness (HSPD-21);

- Executive Order 13527 (“Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures following a Biological Attack”); and National Strategy for Countering Biological Threats.

National biological defence research and development programmes:

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The Department of Defense Chemical and Biological Defense Program develops capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical, biological, and radiological (CBR) threats as part of a layered, integrated defense. The Program is an integral contributor to a global and systems approach for Countering Weapons of Mass Destruction (CWMD), Global Health Security, and other pertinent mission areas.

The Program works to counter biological threats by providing complementary sets of sensors, protective equipment, and medical countermeasures to counter known and unknown threats, including novel and naturally occurring emerging infectious diseases that may also pose a biological weapons threat. Current research focuses on signaling mechanisms between host and bacterial cells; capabilities for pre- and post-exposure therapeutics for bacterial biological select agents and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; the development of rapid and deployable detection assays for troop protection; and medical defenses against neurotoxins.

The Program also works on producing self-disinfecting and/or self-decontaminating materials, as well as developing, producing, and fielding capabilities for sampling, detecting, and identifying biological agents.

Biological defense related work conducted by the Department of Defense is carried out by the military services and biological defense program-focused agencies. These include funding agencies and service laboratories within the Departments of the Air Force, Army, and Navy, and the Defense Threat Reduction Agency/Joint Science and Technology Office, the Joint Program Executive Office for Chemical and Biological Defense, and the Defense Advanced Research Projects Agency.

2. State the total funding for each programme and its source.
$442,196,000 U.S. Department of Defense (DoD)

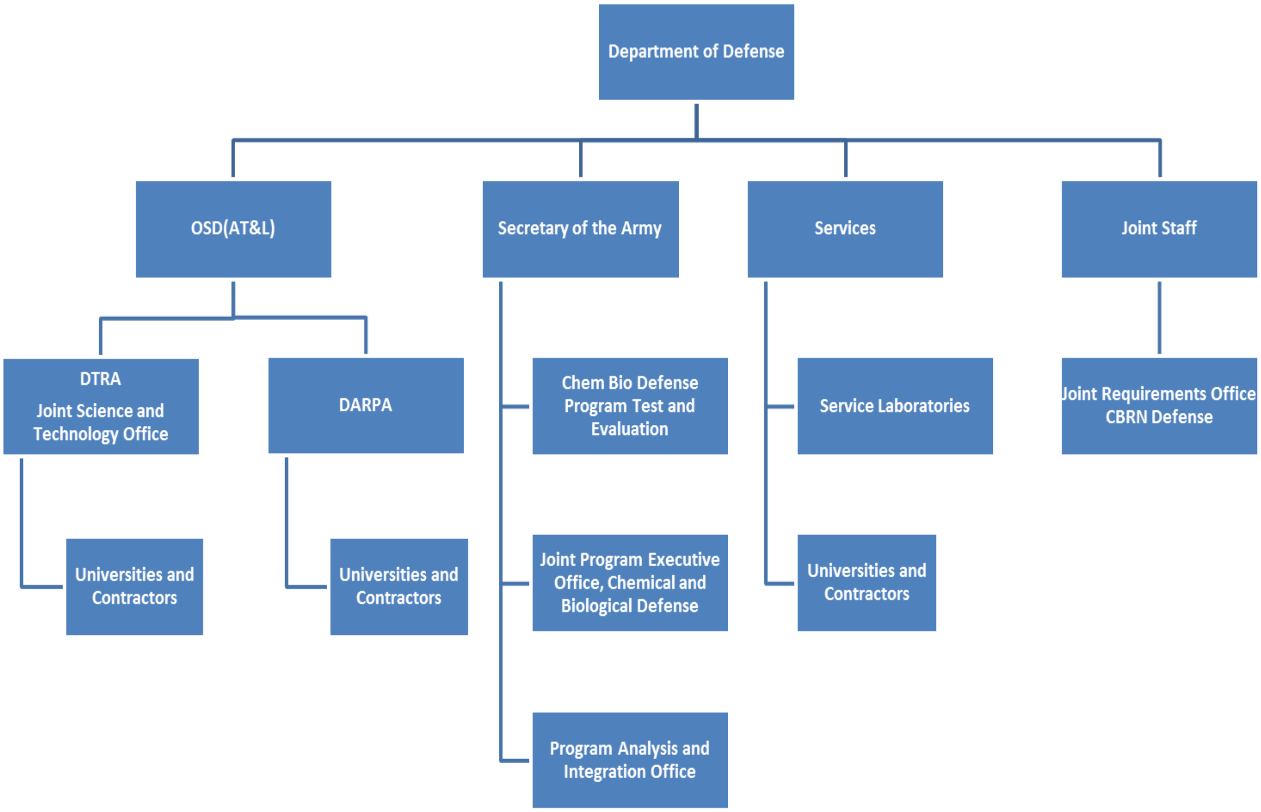
3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
58.7 %

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

- Provide support and capabilities to protect the U.S. Armed Forces against biological warfare threats
- Development, testing, and manufacturing of vaccines, therapeutics, and diagnostic systems
- Development of self-disinfecting and/or self-decontaminating materials
- Development and testing of detection and identification methods, protective equipment, and decontamination systems

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).


Department of Defense
OSD(AT&L)
Secretary of the Army
Services
Joint Staff
DTRA
Joint Science and Technology Office
DARPA
Chem Bio Defense Program Test and Evaluation
Service Laboratories
Joint Requirements Office CBRN Defense
Universities and Contractors
Universities and Contractors
Joint Program Executive Office, Chemical and Biological Defense
Universities and Contractors
Program Analysis and Integration Office

This chart reflects funding relationships

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- Lothar Salomon Life Sciences Test Facility (LSTF) – Page 47
- Naval Medical Research Center (NMRC) – Page 49
- Naval Research Laboratory (NRL) – Page 52
- Naval Surface Warfare Center-Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory – Page 55
- U.S. Army Edgewood Chemical and Biological Center – Page 57
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) – Page 60
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) – Page 63
- Air Force Research Laboratory, 711 HPW, U.S. Air Force School of Aerospace Medicine (USAFSAM) – Page 75
- U.S. Army Natick Soldier Research Development and Engineering Center (NSRDEC) – Page 77

Form A, Part 2 (ii)

National biological defense research and development programmes:

Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities: 1) assistance in the protection of the American water supply, and 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA's responders in the characterization and containment of contamination, and in the remediation of sites following terrorist attacks.

2. State the total funding for the programme and its source.
$6,900,000 U.S. Environmental Protection Agency (EPA)

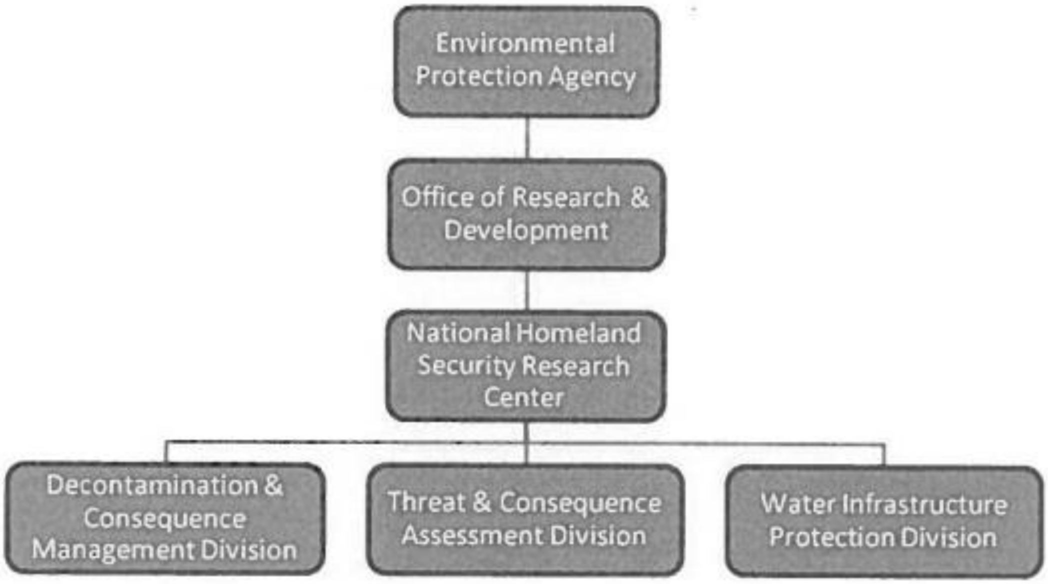
3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defense facilities?
Yes

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
30%

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

To address capabilities related to EPA's indoor/outdoor remediation mission, NHSRC, through intramural and extramural avenues, conducts research related to characterization methods, risk assessment, decontamination methods, and waste management. Specifically the program develops and evaluates 1) sampling and analytical methods for environmental matrices, 2) decontamination methods for complex environments, and 3) treatment methods for solid and liquid waste. Supporting such capabilities, NHSRC has been addressing the fate and transport of biological agents and developing exposure assessment information and methods to support risk assessment decisions.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)


Environmental Protection Agency
Office of Research & Development
National Homeland Security Research Center
Decontamination & Consequence Management Division
Threat & Consequence Assessment Division
Water Infrastructure Protection Division

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defense research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

National biological defence research and development programmes:

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.
The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

The National Institutes of Health (NIH) biodefense program is supported by funding from HHS. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

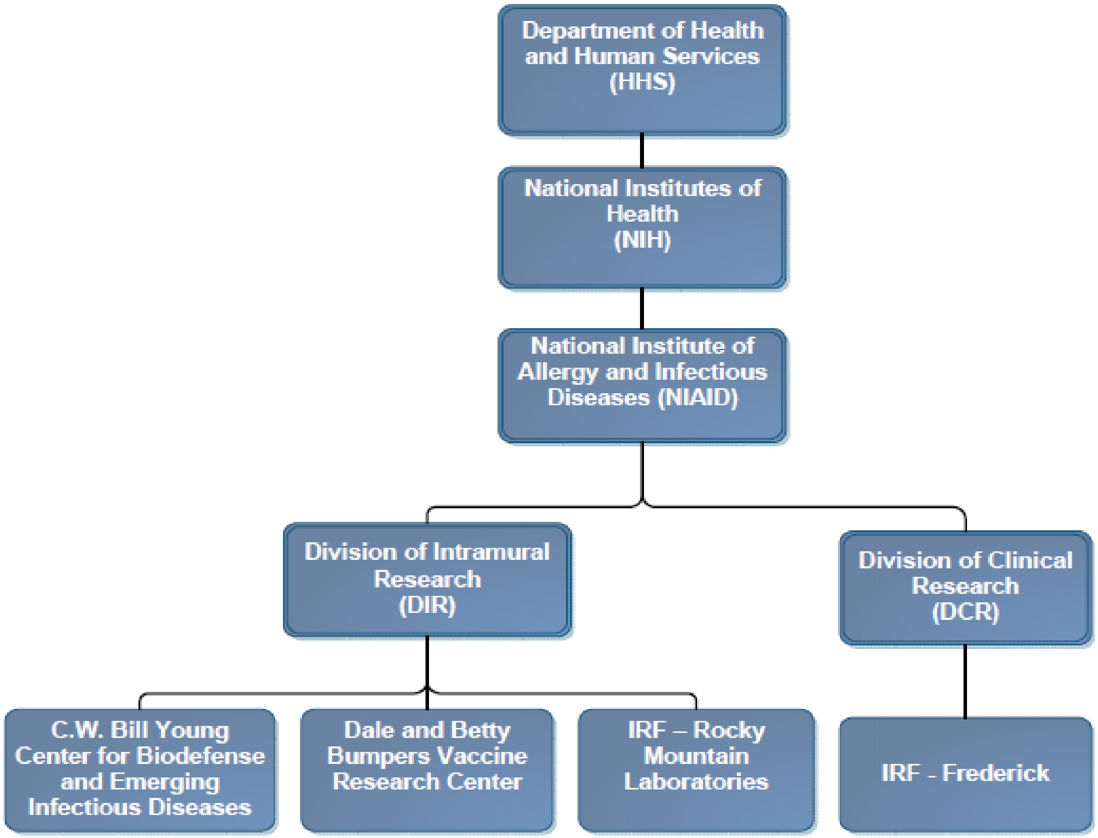
2. State the total funding for each programme and its source.
$81,615,268 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
16.2%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Battelle Memorial Institute facilitates scientific research at the Integrated Research Facility at Fort Detrick (IRF-Frederick), including refinement of animal models to facilitate countermeasure development, with direction from the IRF Scientific Steering Committee.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).


Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Intramural Research (DIR)
Division of Clinical Research (DCR)
C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases
Dale and Betty Bumpers Vaccine Research Center
IRF – Rocky Mountain Laboratories
IRF - Frederick

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML) – Page 116
- Integrated Research Facility at Fort Detrick (IRF - Frederick) – Page 127
- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases – Page 130
- Dale and Betty Bumpers Vaccine Research Center – Page 145

Form A, Part 2 (ii)

National biological defence research and development programmes:

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The objective of the Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory within CDC's National Center for Environmental Health, Division of Laboratory Sciences is to develop toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins.

2. State the total funding for each programme and its source.

$3,395,507	Centers for Disease Control and Prevention (CDC)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

No

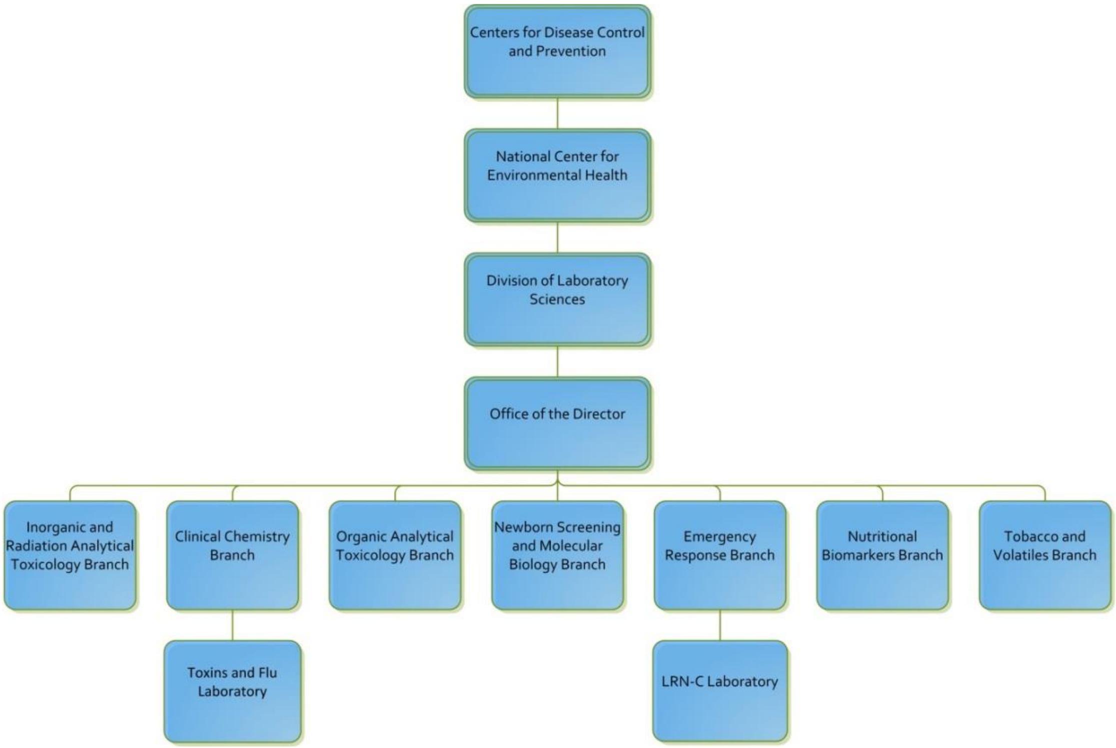
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

N/A

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).


Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Laboratory Sciences
Office of the Director
Inorganic and Radiation Analytical Toxicology Branch
Clinical Chemistry Branch
Organic Analytical Toxicology Branch
Newborn Screening and Molecular Biology Branch
Emergency Response Branch
Nutritional Biomarkers Branch
Tobacco and Volatiles Branch
Toxins and Flu Laboratory
LRN-C Laboratory

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS) – Page 94

National biological defence research and development programmes:

Description

1. **State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

   The activities of the CDC Office of Infectious Disease (OID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents. OID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

   The select agents list is available at:
   http://www.selectagents.gov/SelectAgentsandToxinsList.html

2. **State the total funding for each programme and its source.**

$29,419,394	Centers for Disease Control and Prevention (CDC)

3. **Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

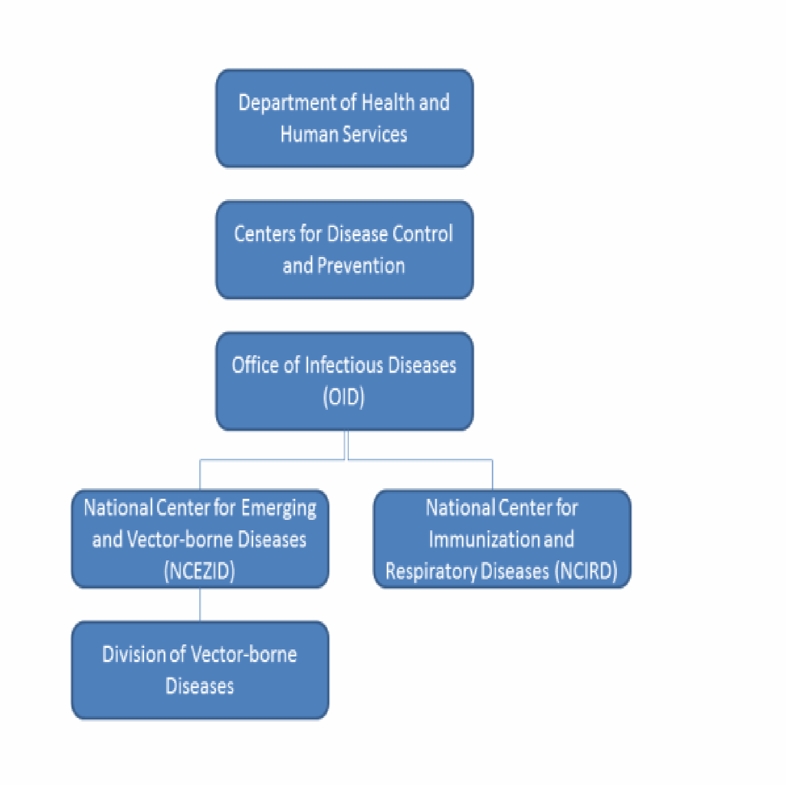
4. **If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?**

   5 %

5. **Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

   Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.

6. **Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).**


Department of Health and Human Services
Centers for Disease Control and Prevention
Office of Infectious Diseases (OID)
National Center for Emerging and Vector-borne Diseases (NCEZID)
National Center for Immunization and Respiratory Diseases (NCIRD)
Division of Vector-borne Diseases

7. **Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- CDC, Office of Infectious Diseases (OID) – Page 98
- CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins – Page 113

National biological defence research and development programmes:

Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

Background

The U.S. Department of Agriculture's Agrigultural Research Service (USDA-ARS) biodefense research program addresses foreign pathogens of plants and animals represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, could have devastating effects on animal or plant health, and in some cases, human health. These devastating effects extend to social and economic impacts -- not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to wheat rust, Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Plant and Animal health officials define an exotic or foreign plant or animal disease as important infectious diseases of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. In addition, zoonotic foreign animal diseases pose a threat to human health and animal production potentially resulting in appreciable costs due to expensive disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a foreign animal disease must be rapidly controlled.

In the United States, control is the first step towards disease eradication. Disease eradication is currently accomplished by eliminating crops or animals, resulting in loss of foods, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a foreign animal disease occurrence in the U.S. will be the loss of export markets. As we move into the 21st century, many new issues and factors are affecting prevention, control, management, and recovery from foreign disease outbreaks. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of plant and animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and countermeasures for the prevention, control and eradication of foreign plant and animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and host responses to many foreign and emerging pathogens is currently insufficient to rapidly control and eradicate disease outbreaks. Currently, effective countermeasures to prevent, detect, control and eradicate foreign plant and animal diseases are inadequate.

Strategic Objectives

- Establish Agricultural Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources
- Access specialized high containment facilities to study zoonotic and emerging diseases
- Develop an integrated animal and microbial genomics research program
- Establish centers of excellence in animal immunology
- Launch a biotherapeutic discovery program providing alternatives to animal drugs
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology
- Develop internationally recognized OIE expert collaborative research laboratories
- Establish a best-in-class training center for our nation's veterinarians and scientists
- Develop a model technology transfer program to achieve the full impact of our research discoveries
- Determine basic knowledge of the biology, pathology, and epidemiology of selected Oomycete pathogens as the basis for development of improved control/management strategies

Research Needs

In order to control foreign animal disease, a wide variety of agent detection platforms needs to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in many countries, there is still much more fundamental knowledge of these agents that is required. There is still a lack of understanding in host range and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g. vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). Lack of reagents, and the lack of stockpiling of diagnostic kits and supplies present vulnerabilities in detection and response preparedness. Effective prevention and control tools need to be developed in order to prepare for the possibility of a foreign animal disease outbreak in the U.S. These could include tools for identifying suitable control strategies which take into account the short amount of time available and the cost of recovery from disease outbreaks. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles and for integrated methods of disease control (including vector control and animal management), which lead to a better capability to regain country disease-free status and retain economic sustainability.

Expected Outputs:

- Better anticipation of introduction of foreign animal diseases
- Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs
- Better capability to produce effective products to control and eliminate foreign animal diseases
- Real-time detection of agents in a wide range of farm matrices
- Searchable databases of genome and proteome information for major known FAD agents
- Improved ability to predict or anticipate emergence or introduction of FAD agents
- Discovery of effective candidate biotherapeutics
- Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA)
- Viable integrated vector control strategies that minimize losses
- In-depth knowledge of pathogen biology, taxonomy, genetics, ecology, and pathology of emerging Oomycete pathogens that can be used to develop novel and effective exclusion, control and management strategies

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa;Orient Point, New York; Athens, Georgia; and Frederick, Maryland.

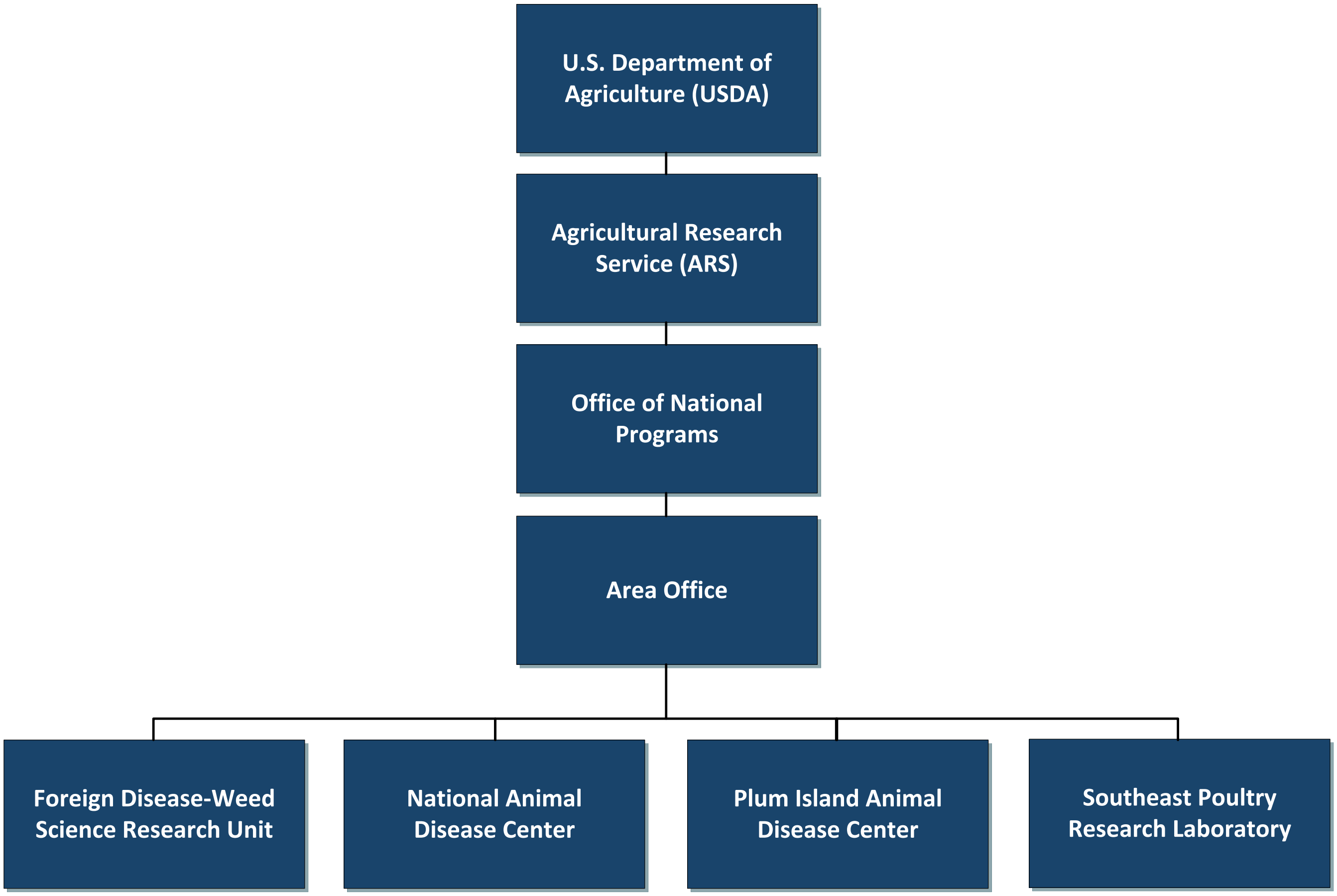
2. State the total funding for the programme and its source.
$ 18,900,000   U.S. Department of Agriculture (USDA)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?
No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
Not Applicable

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.
Not Applicable

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)


U.S. Department of Agriculture (USDA)
Agricultural Research Service (ARS)
Office of National Programs
Area Office
Foreign Disease-Weed Science Research Unit
National Animal Disease Center
Plum Island Animal Disease Center
Southeast Poultry Research Laboratory

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- Plum Island Animal Disease Center (PIADC) – Page 42
- Foreign Disease-Weed Science Research Unit – Page 148
- National Animal Disease Center (NADC) – Page 150
- Southeast Poultry Research Laboratory – Page 153

Form A, Part 2 (ii)

National biological defence research and development programmes:

Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key Department of Homeland Security (DHS) mission areas. This includes efforts to: prevent terrorist attacks, including biological attacks; prevent the unauthorized acquisition, importation, movement, or use of, *inter alia*, biological materials and capabilities within the United States; and reduce the vulnerability of critical infrastructure to terrorist attacks and other hazards. These efforts are further guided by the Homeland Security Presidential Directive – 10, “Biodefense for the 21st Century,” which outlines the four guiding pillars of the DHS biodefense program: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

The goal of the DHS biodefense program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The DHS Biodefense program focuses on scenario modelling, agent release detection, training in responding to biological events, biological countermeasures research, development, testing, and evaluation (RDT&E) efforts, and on the transition of resultant technologies to operational use. The five main areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. federal agencies in overall coordination of national biodefense efforts.

Efforts conducted during 2017 included comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center included biological threat characterization, development of response plans and risk communication and at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, met in 2017 to review all relevant DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

2. State the total funding for the programme and its source.

$93,901,314 U.S. Department of Homeland Security (DHS)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

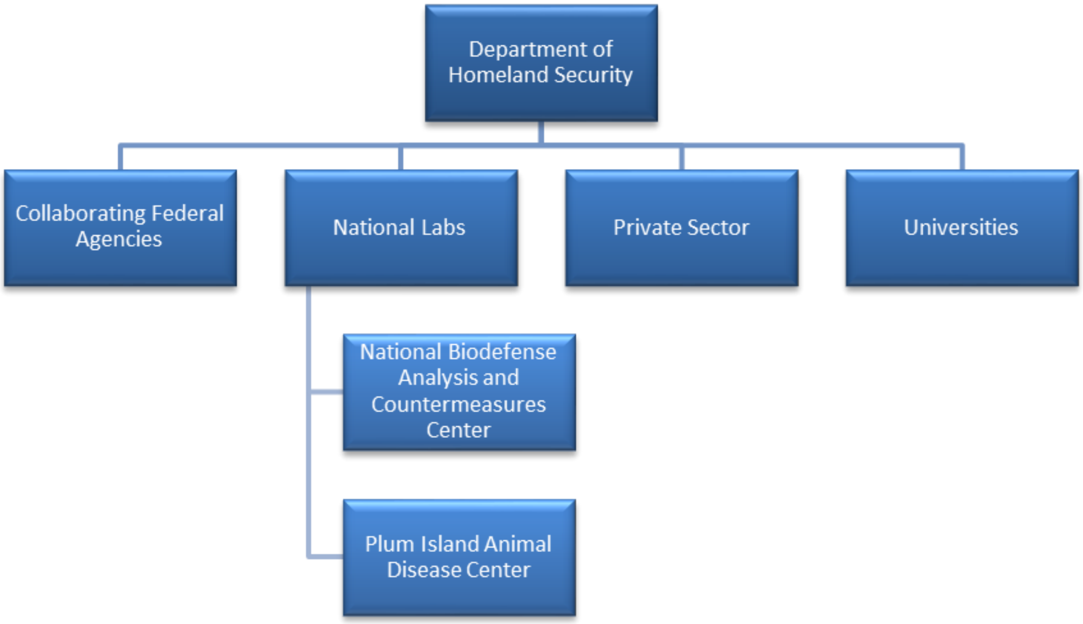
4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

100 %

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

Identical to answer provided in question 1.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).


Department of Homeland Security
Collaborating Federal Agencies
National Labs
Private Sector
Universities
National Biodefense Analysis and Countermeasures Center
Plum Island Animal Disease Center

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- National Biodefense Analysis and Countermeasures Center (NBACC) – Page 39
- Plum Island Animal Disease Center (PIADC) – Page 42

Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2018

National biological defence research and development programme

For each facility detailed on Form A, Part 2 (iii), the entries given for question 3, "Floor area of laboratory areas by containment level (m2)" represent lab space used for biodefense R&D purposes during CY17. Year-to-year variations in programming may result in variations in laboratory space reported rather than alterations to the physical laboratory space.

The U.S. Government identified potential concerns associated with public release of information regarding highly pathogenic microorganisms and toxins at specific facilities. To balance these concerns with a desire to promote transparency, the U.S. public CBM return characterizes microorganisms and toxins studied at each facility on Form A, Part 2 (iii) as Select Agents and/or NIAID Category A pathogens. Furthermore, Appendix B lists the specific microorganisms and toxins studied for biodefense research and development at *all* facilities reported on Form A, part 2 (iii) below.

To maintain a high level of transparency to States Parties, the U.S. makes available, via the restricted-access portion of the ISU website, a Supplement containing information on microorganisms and toxins studied at each individual facility reported on Form A, part 2 (iii).

As stated in the U.S. working paper for the 2013 Meeting of Experts (BWC/MSP/2013/MX/WP.9), "the United States will report microorganisms and toxins that appear on either the Select Agent or the National Institute of Allergy and Infectious Diseases (NIAID) Category A pathogen lists, beginning in 2014." These lists are reproduced in Appendix A for reference.

Biological Select Agents and Toxins (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Possession, use and transfer of Select Agents are regulated by the Select Agent Rules. Detailed information on Select Agents and their regulation can be found at: http://www.selectagents.gov.

The NIAID designated Category A pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Detailed information about NIAID Category A pathogens can be found at: http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
National Biodefense Analysis and Countermeasures Center (NBACC)

2. Where is it located (provide both address and geographical location)?
8300 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,307 m^2
BSL-3:	2,564 m^2
BSL-4:	980 m^2
Total laboratory floor area:	4,851 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 163

(ii) Division of personnel:

Military	0
Civilian	163

(iii) Division of personnel by category:

Scientists	30
Engineers	39
Technicians	54
Administrative and support staff	40

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerobiology, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Immunology, Molecular Biology, Toxicology, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 163

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Homeland Security (DHS)
U.S. Department of Defense (DOD) - partly
U.S. Department of Justice (DoJ)

(vii) What are the funding levels for the following program areas:

Research	$ 8,496,008
Development	$ 12,338,940
Test and evaluation	$ 0
Total	$ 20,834,948

(viii) Briefly describe the publication policy of the facility:

The NBACC publication policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center (FFRDC) engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government laws, regulations and policies including: export control regulations under Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR); the Biological Weapons Convention (BWC), and internal U.S. Department of Homeland Security (DHS) policies. Prior to submittal to journals or release, all publications are reviewed by NBACC and DHS for security, clarity, and accuracy with regard to the description of the work. The DHS Management Directive for Review of External Publications can be found at https://www.dhs.gov/sites/default/files/publications/mgmt_directive_2260.1_review_of_external_publications.pdf.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Bao Y, Amarasinghe GK, Basler CF, et al. Implementation of objective PASC-derived taxon demarcation criteria for official classification of filoviruses. Viruses. 2017 May 11; 9(5): 106. doi: 10.3390/v9050106. http://www.mdpi.com/1999-4915/9/5/106
2. Bazinet AL. Pan-genome and phylogeny of Bacillus cereus sensu lato. BMC Evol Biol. 2017 Aug 2; 17(1): 176. doi: 10.1186/s12862-017-1020-1. https://bmcevolbiol.biomedcentral.com/articles/10.1186/s12862-017-1020-1
3. Dabisch PA, Xu Z, Boydston JA, Solomon J, et al. Quantification of regional aerosol deposition patterns as a function of aerodynamic particle size in rhesus macaques using PET/CT imaging. Inhal Toxicol. 2017 Dec 11; 29(11): 506-515. http://www.tandfonline.com/doi/full/10.1080/08958378.2017.1409848
4. Dawson DG, Bower KA, Burnette CN, Holt RK, et al. Using Telemetry Data to Refine Endpoints for New Zealand White Rabbits Challenged with Bacillus anthracis. J Am Assoc Lab Anim Sci. 2017 Nov 1; 56(6):792-801. http://www.ingentaconnect.com/contentone/aalas/jaalas/2017/00000056/00000006/art00013
5. Fitch JP, Landon P. Laboratory Aerosol Hazard Assessment Utilizing Material Balance Models. Applied Biosafety. 2017 Mar 1; 22(1): 21-32. http://journals.sagepub.com/doi/full/10.1177/1535676017693888
6. Kochel TJ, Kocher GA, Ksiazek TG, Burans JP. Evaluation of TRIzol LS Inactivation of Viruses. Applied Biosafety. 2017 Jun 21; 22(2): 52–55. http://journals.sagepub.com/doi/full/10.1177/1535676017713739
7. Koren S, Walenz BP, Berlin K, et al. Canu: scalable and accurate long-read assembly via adaptive k-mer weighting and repeat separation. Genome Res. 2017 May; 27(5): 722-736. http://genome.cshlp.org/content/early/2017/03/15/gr.215087.116
8. Landon P, Wood S, Bower K, Heil R, et al. Performance characteristics of a primary containment system for large animals in animal biosafety level 4. Applied Biosafety. 2017 Mar 1; 22(1): 14-20. http://journals.sagepub.com/doi/10.1177/1535676016683172
9. Schooley RT, Biswas B, Gill JJ, et al. Development and Use of Personalized Bacteriophage-Based Therapeutic Cocktails To Treat a Patient with a Disseminated Resistant Acinetobacter baumannii Infection. Antimicrob Agents Chemother. 2017 Oct; 61(10): e00954-17. doi: 10.1128/AAC.00954-17. http://aac.asm.org/content/early/2017/08/08/AAC.00954-17.abstract

10. Venkateswaran K, Checinska Sielaff A, Ratnayake S, et al. Draft Genome Sequences from a Novel Clade of Bacillus cereus Sensu Lato Strains, Isolated from the International Space Station. Genome Announc. 2017 Aug 10; 5(32): e00680-17. doi: 10.1128/genomeA.00680-17. http://genomea.asm.org/content/5/32/e00680-17.abstract
11. Venkateswaran K, Singh NK, Sielaff AC, et al. Non-Toxin-Producing Bacillus cereus Strains Belonging to the B. anthracis Clade Isolated from the International Space Station. mSystems. 2017 Jun 27; 2(3): e00021-17. doi: 10.1128/mSystems.00021-17. http://msystems.asm.org/content/2/3/e00021-17

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[1] and/or toxins studied, as well as outdoor studies of biological aerosols:

***Objectives*:** The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution investigations. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

***Microorganisms and/or Toxins Studied*:** Select Agents (HHS, Overlap), Select Toxins (HHS), simulants, NIAID Category A pathogens.

***Outdoor Studies*:** No outdoor studies performed.

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[1] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Plum Island Animal Disease Center (PIADC)

2. Where is it located (provide both address and geographical location)?

40550 Route 25, Orient Point, New York 11957

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	292 m^2
BSL-3:	18,046 m^2
BSL-4:	0 m^2
Total laboratory floor area:	18,338 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 362

(ii) Division of personnel:

Military	0
Civilian	362

(iii) Division of personnel by category:

Scientists	57
Engineers	4
Technicians	13
Administrative and support staff	288

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Biological Science, Chemistry, Engineering, Microbiology, Molecular Biology, Computational Biology, Pathology, Veterinary Medicine

(v) Are contractor staff working in the facility? If so, provide an approximate number:

Yes Number: 248

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Agriculture (USDA)
U.S. Department of Homeland Security (DHS)

(vii) What are the funding levels for the following program areas:

Research	$ 4,130,372
Development	$ 2,700,000
Test and evaluation	$ 4,391,893
Total	$ 11,222,265

(viii) Briefly describe the publication policy of the facility:

DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. USDA Agricultural Research Service (ARS) has several publication policies: 1) Policy Number 150.1 "Dissemination of Public Information by ARS," http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf ; 2) Number 113.1 "Publishing (Print and Electronic), www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf; and 3) Number 152.1 "Procedures for Publishing Manuscripts and Abstracts with Non-USDA Publishers (Outside Publishing) http://www.afm.ars.usda.gov/ppweb/pdf/152-01.pdf.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Ahmed Z, Pauszek SJ, Ludi A, et al. Genetic diversity and comparison of diagnostic tests for characterization of foot-and-mouth disease virus strains from Pakistan 2008-2012. Transbound Emerge Dis. 2017 Oct 16. doi: 10.1111/tbed.12737 http://onlinelibrary.wiley.com/doi/10.1111/tbed.12737/full
2. Arzt J, Brito B, Pauszek SJ, et al. Genome sequence of foot-and-mouth disease virus serotype O lineage Ind-2001d collected in Vietnam in 2015. Genome Announc. 2017 May 4; 5(18): e00223-17. doi: 10.1128/genomeA.00223-17. http://genomea.asm.org/content/5/18/e00223-17.full
3. Arzt J, Pacheco JM, Stenfeldt C, Rodriguez LL. Pathogenesis of virulent and attenuated foot-and-mouth disease virus in cattle. Virol J. 2017 May 2; 14(1): 89. doi: 10.1186/s12985-017-0758-9. https://virologyj.biomedcentral.com/articles/10.1186/s12985-017-0758-9
4. Barrera J, Brake DA, Kamicker BJ, et al. Safety profile of a replication-deficient human adenovirus-vectored foot-and-mouth disease virus serotype A24 subunit vaccine in cattle. Transbound Emerg Dis. 2017 Oct 27. doi: 10.1111/tbed.12724. http://onlinelibrary.wiley.com/doi/10.1111/tbed.12724/full
5. Barrette RW, Rowland JM, Grau FR, McIntosh MT. Development of a feature and template-assisted assembler and application to the analysis of a foot-and-mouth disease virus genotyping microarray. PLoS One. 2017 Jan 3; 12(1): e0166870. doi: 10.1371/journal.pone.0166870. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0166870
6. Bergeron HC, Glas PS, Schumann KR. Diagnostic specificity of the African swine fever virus antibody detection enzyme-linked immunosorbent assay in feral and domestic pigs in the United States. Transbound Emerg Dis. 2017 Dec; 64(6): 1665–1668. http://onlinelibrary.wiley.com/doi/10.1111/tbed.12717/full
7. Borca MV, O'Donnell V, Holinka LG, et al. Development of a fluorescent ASFV strain that retains the ability to cause disease in swine. Sci Rep. 2017 Apr 24; 7: 46747. doi: 10.1038/srep46747. https://www.nature.com/articles/srep46747
8. Brito BP, Mohapatra JK, Subramaniam S, et al. Dynamics of widespread foot-and-mouth disease virus serotypes A, O and Asia-1 in southern Asia: A Bayesian phylogenetic perspective. Transbound Emerg Dis. 2017 Dec 17. doi: 10.1111/tbed.12791 http://onlinelibrary.wiley.com/doi/10.1111/tbed.12791/full
9. Brito B, Pauszek SJ, Eschbaumer M, et al. Phylodynamics of foot-and-mouth disease virus O/Panasia in Vietnam 2010–2014. Vet Res. 2017 Apr 13; 48(1): 24. doi: 10.1186/s13567-017-0424-7. https://veterinaryresearch.biomedcentral.com/articles/10.1186/s13567-017-0424-7
10. Cacciabue M, García-Núñez MS, Delgado F, et al. Differential replication of foot-and-mouth disease viruses in mice determine lethality. Virology. 2017 Sep; 509: 195-204. https://www.sciencedirect.com/science/article/pii/S0042682217301903?via%3Dihub
11. Das A, Deng MY, Babiuk S, McIntosh MT. Modification of two capripoxvirus quantitative real-time PCR assays to improve diagnostic sensitivity and include beta-actin as an internal

positive control. J Vet Diagn Invest. 2017 May; 29(3): 351-356. http://journals.sagepub.com/doi/10.1177/1040638717695609

12. Das A, Ward G, Lowe A, et al. Development and validation of a highly sensitive real-time PCR assay for rapid detection of parapoxviruses. J Vet Diagn Invest. 2017 Jul; 29(4): 499-507. http://journals.sagepub.com/doi/10.1177/1040638716680676
13. Diaz-San Segundo F, Medina GN, Stenfeldt C, Arzt J, de Los Santos T. Foot-and-mouth disease vaccines. Vet Microbiol. 2017 Jul; 206: 102-112. https://www.sciencedirect.com/science/article/pii/S0378113516308033?via%3Dihub
14. Fernandez-Sainz I, Medina GN, Ramirez-Medina E, et al. Adenovirus-vectored foot-and-mouth disease vaccine confers early and full protection against FMDV O1 Manisa in swine. Virology. 2017 Feb; 502: 123-32. https://www.sciencedirect.com/science/article/pii/S0042682216304032?via%3Dihub
15. Gutkoska J, LaRocco M, Ramirez-Medina E, de Los Santos T, Lawrence P. Host microRNA-203a is antagonistic to the progression of foot-and-mouth disease virus infection. Virology. 2017 Apr; 504: 52-62. https://www.sciencedirect.com/science/article/pii/S0042682217300284?via%3Dihub
16. Hayer SS, Ranjan R, Biswal JK, et al. Quantitative characteristics of the foot-and-mouth disease carrier state under natural conditions in India. Transbound Emerg Dis. 2017 March 2. doi: 10.1111/tbed.12627. http://onlinelibrary.wiley.com/doi/10.1111/tbed.12627/full
17. Hayer SS, VanderWaal K, Ranjan R, et al. Foot-and-mouth disease virus transmission dynamics and persistence in a herd of vaccinated dairy cattle in India. Transbound Emerg Dis. 2017 Dec 5. doi: 10.1111/tbed.12774 http://onlinelibrary.wiley.com/doi/10.1111/tbed.12774/full
18. Holinka LG, O’Donnell V, Risatti GR, et al. Early protection events in swine immunized with an experimental live attenuated classical swine fever marker vaccine, FlagT4G. PLoS One. 2017 May 24; 12(5): e0177433. doi: 10.1371/journal.pone.0177433. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177433
19. Kenney M, Waters RA, Rieder E, et al. Enhanced sensitivity in detection of antiviral antibody responses using biotinylation of foot-and-mouth disease virus (FMDV) capsids. J Immunol Methods. 2017 Nov; 450: 1-9. https://www.sciencedirect.com/science/article/pii/S0022175917302144?via%3Dihub
20. Kloc A, Diaz-San Segundo F, Schafer EA, et al. Foot-and-mouth disease virus 5'-terminal S fragment is required for replication and modulation of the innate immune response in host cells. Virology. 2017 Sep 26; 512: 132-143. https://www.sciencedirect.com/science/article/pii/S0042682217302994?via%3Dihub
21. Lawrence P, Rieder E. Insights into Jumonji C-domain containing protein 6 (JMJD6): a multifactorial role in foot-and-mouth disease virus replication in cells. Virus Genes. 2017 Jun; 53(3): 340-351. https://link.springer.com/article/10.1007%2Fs11262-017-1449-8
22. Lokhandwala S, Waghela SD, Bray J, et al. Adenovirus-vectored novel African swine fever virus antigens elicit robust immune responses in swine. PLoS One. 2017 May 8; 12(5): e0177007. doi: 10.1371/journal.pone.0177007. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177007
23. Lopera-Madrid J, Osorio JE, He Y, et al. Safety and immunogenicity of mammalian cell derived and Modified Vaccinia Ankara vectored African swine fever subunit antigens in swine. Vet Immunol Immunopathol. 2017 Mar; 185: 20–33. https://www.sciencedirect.com/science/article/pii/S0165242717300351?via%3Dihub
24. Medina GN, Knudsen GM, Greninger AL, et al. Interaction between FMDV Lpro and transcription factor ADNP is required for optimal viral replication. Virology. 2017 May; 505: 12-22. https://www.sciencedirect.com/science/article/pii/S0042682217300508?via%3Dihub
25. Neira V, Brito B, Mena J, et al. Epidemiological investigations of the introduction of porcine reproductive and respiratory syndrome virus in Chile, 2013-2015. PLoS One. 2017 Jul 25;

12(7): e0181569. doi: 10.1371/journal.pone.0181569. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181569

26. Pauszek SJ, Bertram MR, Vu LT, et al. Genome sequences of seven foot-and-mouth disease virus isolates collected from serial samples from one persistently infected carrier cow in Vietnam. Genome Announc. 2017 Aug 24; 5(34): e00849-17. doi: 10.1128/genomeA.00849-17. http://genomea.asm.org/content/5/34/e00849-17.full
27. Puckette M, Burrage T, Neilan JG, Rasmussen M. Evaluation of Gaussia luciferase and foot-and-mouth disease virus 2A translational interrupter chimeras as polycistronic reporters for transgene expression. BMC Biotechnol. 2017 Jun 12; 17(1): 52. doi: 10.1186/s12896-017-0367-0. https://bmcbiotechnol.biomedcentral.com/articles/10.1186/s12896-017-0367-0
28. Puckette M, Clark BA, Smith JD, et al. Foot-and-mouth disease (FMD) virus 3C protease mutant L127P: Implications for FMD vaccine development. J Virol. 2017 Nov; 91(22): e00924-17. doi: 10.1128/JVI.00924-17. http://jvi.asm.org/content/91/22/e00924-17.full
29. Rai DK, Diaz-San Segundo F, Campagnola G, et al. Attenuation of foot-and-mouth disease virus by engineering viral polymerase fidelity. J Virol. 2017 Aug 1; 91(15): e00081-17. doi: 10.1128/JVI.00081-17. http://jvi.asm.org/content/91/15/e00081-17.full
30. Rivas J, Neira V, Mena J, et al. Identification of a divergent genotype of equine arteritis virus from South American donkeys. Transbound Emerg Dis. 2017 Dec; 64(6): 1655-1660. http://onlinelibrary.wiley.com/doi/10.1111/tbed.12703/full
31. Singanallur NB, Pacheco JM, Arzt J, et al. Efficacy of a high potency O1 Manisa monovalent vaccine against heterologous challenge with foot-and-mouth disease virus of O/SEA/Mya-98 lineage in sheep. Antiviral Res. 2017 Sep; 145: 114-122. https://www.sciencedirect.com/science/article/pii/S0166354217302632?via%3Dihub
32. Sreenivasa BP, Mohapatra JK, Pauszek SJ, et al. Recombinant human adenovirus-5 expressing capsid proteins of Indian vaccine strains of foot-and-mouth disease virus elicits effective antibody response in cattle. Vet Microbiol. 2017 May; 203: 196-201. https://www.sciencedirect.com/science/article/pii/S0378113517300251?via%3Dihub
33. Stenfeldt C, Arzt J, Smoliga G, et al. Proof-of-concept study: profile of circulating microRNAs in Bovine serum harvested during acute and persistent FMDV infection. Virol J. 2017 Apr 7; 14(1): 71. doi: 10.1186/s12985-017-0743-3. https://virologyj.biomedcentral.com/articles/10.1186/s12985-017-0743-3
34. Stenfeldt C, Eschbaumer M, Smoliga GR, et al. Clearance of a persistent picornavirus infection is associated with enhanced pro-apoptotic and cellular immune responses. Sci Rep. 2017 Dec 19; 7(1): 17800. doi: 10.1038/s41598-017-18112-4. https://www.nature.com/articles/s41598-017-18112-4
35. Velazquez-Salinas L, Isa P, Pauszek SJ, Rodriguez LL. Complete genome sequences of two vesicular stomatitis virus isolates collected in Mexico. Genome Announc. 2017 Sep 14; 5(37): e01006-17. doi: 10.1128/genomeA.01006-17. http://genomea.asm.org/content/5/37/e01006-17.full
36. Velazquez-Salinas L, Naik S, Pauszek S, et al. Oncolytic recombinant vesicular stomatitis virus (VSV) is nonpathogenic and non-transmissible in pigs, a natural host of VSV. Hum Gene Ther Clin Dev. 2017 Jun; 28(2): 108-115. http://online.liebertpub.com/doi/10.1089/humc.2017.015
37. Vu LT, Long NT, Brito B, et al. First detection of foot-and-mouth disease virus O/Ind-2001d in Vietnam. PLoS One. 2017 Jun 9; 12(6): e0177361. doi: 10.1371/journal.pone.0177361. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177361

5. **Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[2] and/or toxins studied, as well as outdoor studies of biological aerosols**:

Objectives: PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock, including foot-and-mouth disease, in the United States. Technologies researched and developed are vaccines, antivirals, and diagnostic methods.

Microorganisms and/or Toxins Studied: Select Agents (USDA).

Outdoor Studies: No outdoor studies performed

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[2] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Lothar Salomon Test Facility (LSTF)

2. Where is it located (provide both address and geographical location)?

2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022-5006

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	710 m^2
BSL-3:	336 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,046 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	8

(ii) Division of personnel:

Military	0
Civilian	8

(iii) Division of personnel by category:

Scientists	6
Engineers	0
Technicians	2
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Aerobiology, Bacteriology, Biochemistry, Immunology, Microbiology, Molecular Biology, Toxicology, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number:

Yes Number: 8

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DoD) – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 0
Development	$ 0
Test and evaluation	$ 272,140
Total	$ 272,140

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):
None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[3] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Testing battlefield detection and identification methods, protective equipment, and decontamination systems, including interferent testing of biological detectors and to develop/validate aerosol particle dispersion models to enhance countermeasure response.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens, Select Agents (HHS, Overlap) and Toxins, simulants

Outdoor Studies: Yes - using simulants

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[3] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. **What is the name of the facility?**
Naval Medical Research Center (NMRC)

2. **Where is it located (provide both address and geographical location)?**
8400 Research Plaza, Fort Detrick, Maryland 21702

3. **Floor area of laboratory areas by containment level (m^2):**

BSL-2:	2,000 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,000 m^2

4. **The organizational structure of each facility:**

(i) **Total number of personnel:** 58

(ii) **Division of personnel:**

Military	10
Civilian	48

(iii) **Division of personnel by category:**

Scientists	19
Engineers	0
Technicians	32
Administrative and support staff	7

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**
Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
Yes Number: 42

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Defense – wholly

(vii) **What are the funding levels for the following program areas:**

Research	$ 4,725,008
Development	$ 0
Test and evaluation	$ 0
Total	$ 4,725,008

(viii) **Briefly describe the publication policy of the facility:**
Professional scientists are encouraged to publish worthy papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Li PE, Lo C-C, Anderson JJ, Davenport KW, Bishop-Lilly KA, Xu Y, Ahmed S, Feng S, Mokashi VP, Chain PS. Enabling the democratization of the genomics revolution with a fully integrated web-based bioinformatics platform. Nucleic Acids Res. 2017 Jan 9;45(1):67-80. doi: 10.1093/nar/gkw1027. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/pmid/27899609/
2. Cer RZ, Herrera-Galeano JE, Frey KG, Schully KL, Luu TV, Pesce J, Mokashi VP, Keane-Myers AM, Bishop-Lilly KA. Differential microRNA analyses of Burkholderia pseudomallei and Franciscella tularensis-exposed hPBMCs reveal potential biomarkers. Int J Genomics. 2017;2017:6489383. doi: 10.1155/2017/6489383. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5534298/
3. Duplessis C, Biswas B, Hanisch B, Perkins M, Henry M, Quinones J, Wolfe D, Estrella L, Hamilton. Refractory Pseudomonas bacteremia in a 2-year-old sterilized by bacteriophage therapy. J Pediatric Infect Dis Soc. 2017 Jul 22. doi: 10.1093/jpids/pix056. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28992111
4. Millar EV, Rice GK, Elassal EM, Schlett CD, Bennett JW, Redden CL, Mor D, Law NN, Tribble DR, Hamilton TC, Ellis MW, Bishop-Lilly KA. Genomic characterization of USA300 MRSA to evaluate interclass transmission and recurrence of SSTI among high risk military trainees. Clin Infect Dis. 2017 Aug 1;65(3):461-468. doi: 10.1093/cid/cix327 https://academic.oup.com/cid/article-abstract/65/3/461/3737616?redirectedFrom=fulltext
5. Schully KL, Berjohn CM, Prouty AM, Fitkariwala A, Som T, Sieng D, Gregory M, Vaughn A, Kheng S, Te V, Duplessis CA, Lawler JV, Clark DV. Melioidosis in lower provincial Cambodia: A case series form a prospective study of sepsis in Takeo Province. PLoS Negl Trop Dis. 2017 Sep 13; 11(9): e0005923. doi: 10.1371/journal.pntd.0005923. eCollection 2017 Sep. http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005923
6. Schooley RT, Biswas B, Gill JJ, Hernandez-Morales A, Lancaster J, Lessor L, Barr JJ, Reed SL, Rohwer F, Benler S, Segall AM, Taplitz R, Smith DM, Kerr K, Kumaraswamy M, Nizet V, Lin L, McCauley M, Strathdee SA, Benson CA, Pope RK, Leroux BM, Picel AC, Mateczun AJ, Cilwa KE, Regeimbal JM, Estrella L, Wolfe DM, Henry M, Quinones J, Salka S, Bishop-Lilly KA, Young R, Hamilton T. Development and use of personalized bacteriophage-based therapeutic cocktails to treat a patient with a disseminated resistant Acinetobacter baumannii infection. Antimicrob Agents Chemother. 2017 Sep 22; 61(10). Pii: e00954-17. doi: 10.1128/AAC.00954-17. https://www.ncbi.nlm.nih.gov/pubmed/28807909

4. **Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[4] and/or toxins studied, as well as outdoor studies of biological aerosols:**

Objectives: The goal of the program is the development of rapid and deployable detection assays to protect deployed troops. During 2017, we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of new diagnostic assays and better treatment strategies against relevant infectious diseases. Additional information is available at http://www.med.navy.mil/sites/nmrc/NMRC/Pages/NMRC.aspx

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens and B Priority pathogens

Outdoor Studies: None

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[4] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Research Laboratory (NRL)

2. Where is it located (provide both address and geographical location)?
4555 Overlook Ave., SW, Washington, D.C. 20375

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	578 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	578 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	31

(ii) **Division of personnel:**

Military	0
Civilian	31

(iii) **Division of personnel by category:**

Scientists	27
Engineers	1
Technicians	3
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**
Biochemistry, Biophysics, Chemical Engineering, Chemistry, Electrical Engineering, Immunology, Mechanical Engineering, Microbiology, Molecular Biology, Physics

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
Yes Number: 4

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Defense – Wholly

(vii) **What are the funding levels for the following program areas:**

(viii)	**Research**	$ 3,289,000
(ix)	**Development**	$ 2,208,000
(x)	**Test and evaluation**	$ 0
(xi)	**Total**	$ 5,497,000

(xii) **Briefly describe the publication policy of the facility:**
Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before

submission. Release of DoD publications is guided by DoD Directive 5230.09 (Clearance of DoD Information for Public Release, http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29 (Security and Policy Review of DoD Information for Public Release, http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf) for publishing information related to biological defense efforts. Public release of unclassified technical information is subject to sponsor approval.

(xiii) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Liu, J.L., Shriver-Lake, L.C., Anderson, G.P., Zabetakis, D., Goldman, E.R. Selection, characterization, and thermal stabilization of llama single domain antibodies towards Ebola virus glycoprotein. Microbial Cell Factories. 2017; 16(1):223. DOI: 10.1186/s12934-017-0837-z. https://www.ncbi.nlm.nih.gov/pubmed/29233140
2. Goldman, E.R., Liu, J.L., Zabetakis, D., Anderson, G.P. Enhancing stability of camelid and shark single domain antibodies: An Overview. Frontiers in Immunology. 2017; 8:865. DOI: 10.3389/fimmu.2017.00865. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5524736/
3. Shriver-Lake, L.C., Zabetakis, D., Goldman, E.R., Anderson, G.P. Evaluation of anti-botulinum neurotoxin single domain antibodies with additional optimization for improved production and stability. Toxicon. 2017 Sep 1; 135:51-58. DOI: 10.1016/j.toxicon.2017.06.002. https://www.ncbi.nlm.nih.gov/pubmed/28587791
4. Turner, K.B., Hardy, S. Liu, J.L., Zabetakis, D., Brozozog Lee, P.A., Goldman, E.R., Anderson, G.P. Pairing alpaca and llama-derived single domain antibodies to enhance immunoassays for ricin Antibodies. 2017 Feb 2; 6(1):3. DOI: 10.3390/antib6010003 http://www.mdpi.com/2073-4468/6/1/3
5. Shriver-Lake, L.C., Goldman, E.R., Zabetakis, D., Anderson, G.P. Improved production of single domain antibodies with two disulfide bonds by co-expression of chaperone proteins in the Escherichia coli periplasm. J. Immunological Methods. 2017 Apr; 443: 64-67. DOI: 10.1016/j.jim.2017.01.007. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28131818
6. Anderson, G.P., Liu, J.L., Zabetakis, D., Legler, P.M., Goldman, E.R. Label free checkerboard assay to determine overlapping epitopes of Ebola virus VP-40 antibodies using surface plasmon resonance. J. Immunological Methods. 2017 Mar; 442:42-48. DOI: 10.1016/j.jim.2017.01.005. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28109682
7. Sivaprakasam, V., Hart, M.B., Eversole, J.D. Surface enhanced raman spectroscopy of individual suspended aerosol particles. J. Phys. Chem. C. 2017 Sept 14; 121:22326-22334. DOI: 10.1021/acs.jpcc.7b05310. https://pubs.acs.org/doi/abs/10.1021/acs.jpcc.7b05310
8. Lane, P.A., Hart, M.B., Tucker, J.E., Jain, V., Eversole, J.D. Characterization of single particle aerosols by elastic light scattering at multiple wavelengths. J. Quant. Spectrosc. Radiat. Transfer. 2017 Dec; 208:188-195. [Epub ahead of print] https://doi.org/10.1016/j.jqsrt.2017.12.017.
9. Giles, S.L.; Lundin, J.G.; Balow, R.B.; Pehrsson, P.E.; Wynne, J.H., Comparative roles of Zr4+ and Ni2+ wells-dawson hetero-metal substituted polyoxometalates on oxidation

of chemical contaminants. Applied Catalysis A: General. 2017 Jul 25; 542:306-310. http://dx.doi.org/doi:10.1016/j.apcata.2017.06.002

10. Hebert CG, Hart S, Leski TA, Terray A, Lu Q. Label-free detection of Bacillus anthracis spore uptake in macrophage cells using analytical optical force measurements. Anal Chem. 2017; 89(19):10296-10302. https://pubs.acs.org/doi/10.1021/acs.analchem.7b01983

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[5] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The objectives of research at NRL are to develop and test reliable systems for the detection of chemical and biological (CB) warfare agents in order to provide early warning and contamination avoidance information. Additional information is available at http://www.nrl.navy.mil/research/

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens and B Priority pathogens, simulants.

Outdoor Studies: None

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[5] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory

2. Where is it located (provide both address and geographical location)?

6149 Welsh Road, Dahlgren, Virginia 22448

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	180 m^2
BSL-3:	27 m^2
BSL-4:	0 m^2
Total laboratory floor area:	207 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	176

(ii) Division of personnel:

Military	0
Civilian	176

(iii) Division of personnel by category:

Scientists	67
Engineers	48
Technicians	15
Administrative and support staff	46

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Aerospace Engineering, Chemical Engineering, Chemistry, Computer Engineering, Computer Science, Electronic Engineering, Industrial Engineering, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Toxicology

(v) Are contractor staff working in the facility? If so, provide an approximate number:

Yes Number: 26

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DoD) – partly
Private Sector Companies
Internal (Laboratory Directed Research and Development [LDRD])
Other Governmental Agencies

(vii) What are the funding levels for the following program areas:

Research	$ 3,218,231
Development	$ 5,882,710
Test and evaluation	$ 421,096
Total	$ 9,522,037

(viii) Briefly describe the publication policy of the facility:

Employees are encouraged to publish. Employees must follow appropriate U.S. DoD guidelines for publishing information related to biological defense efforts and have all publications approved. Public release of unclassified technical information is subject to sponsor approval.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Staab A, Plaut RD, Pratt C, Lovett SP, Wiley MR, Biggs TD, et. al. Whole-genome sequences of variants of Bacillus anthracis Sterne and their toxin gene deletion mutants. Genome Announcements. 2017; Nov 9;5(45):e01231-17. http://genomea.asm.org/content/5/45/e01231-17

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[6] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools and consequence management planning.

Microorganisms and/or Toxins Studied: Overlap Select Agent + NIAID Category A Simulant

Outdoor Studies: Performance testing of a prototype biosurveillance system using a biological simulant.

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[6] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

U.S. Army Edgewood Chemical and Biological Center

2. Where is it located (provide both address and geographical location)?

5183 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5424

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	532 m^2
BSL-3:	177 m^2
BSL-4:	0 m^2
Total laboratory floor area:	709 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel**	80

(ii)	**Division of personnel:**	
	Military	0
	Civilian	80

(iii)	**Division of personnel by category:**	
	Scientists	40
	Engineers	0
	Technicians	36
	Administrative and support staff	4

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Aerobiology, Aerospace Engineering, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Physiology, Toxicology, Toxinology, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes. Number: 5

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U. S. Department of Defense (DoD) – Wholly

(vii) What are the funding levels for the following programme areas:

Research	$1,426,000
Development	$21,545,000
Test and evaluation	$0
Total	$22,971,000

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)

1. Angelini D, Harris J, Smith L, Rastogi V, Williams K, Burton L, Rastogi P. Evaluation of commercial-off-the-shelf materials for the preservation of gram positive vegetative cells. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States. 2017; ECBC-TR-1435. http://www.dtic.mil/dtic/tr/fulltext/u2/1027073.pdf
2. Bernhards RC, Cote CK, Amemiya K, Waag DM, Klimko CP, Worsham PL, Welkos, SL. Characterization of in vitro phenotypes of Burkholderia pseudomallei and Burkholderia mallei strains potentially associated with persistent infection in mice. Arch Microbiol. 2017 Mar; 199(2):277-301. doi: 10.1007/s00203-016-1303-8. https://link.springer.com/content/pdf/10.1007%2Fs00203-016-1303-8.pdf
3. Calm A, Hofmann ER, Boyd G, Mangaya C, Betts K. Pilot scale production and testing of a recombinant staphylococcal enterotoxin (seb) triple mutant. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States, 2017; ECBC-TR-1471. http://www.dtic.mil/dtic/tr/fulltext/u2/1039416.pdf
4. Cole S, Blum S, Miklos A, Maciel J, Funk V. Purification of recombinant Ebola virus glycoprotein and Vp40 from a human cell line. Edgewood Chemical Biological Center Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States, Excet, Inc. 2017; ECBC-TR-1389. http://www.dtic.mil/dtic/tr/fulltext/u2/1034262.pdf
5. Kesavan JS, Humphreys PD, Bottiger JR, Valdes ER, Rastogi VK, Knox CK. Deposition method, relative humidity, and surface property effects of bacterial spore reaerosolization via pulsed air jet. Aerosol Sci Technol. 2017 Jun 13;51(9):1027-34.

doi:10.1080/02786826.2017.1335389. http://www.tandfonline.com/doi/full/10.1080/02786826.2017.1335389

6. Kesavan J, Humphreys P, Nasr B, Ahmadi G, Knox CK, Valdes E, et al. Experimental and computational study of reaerosolization of 1 to 5 mu m PSL microspheres using jet impingement. Aerosol Sci Technol. 2017;51(3):377-87. doi: 10.1080/02786826.2016.1265081. http://www.tandfonline.com/doi/full/10.1080/02786826.2016.1265081
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8. Rastogi V, Smith L, Wallace L. Comparative evaluation of quantitative test methods for gases on a hard surface. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States. 2017; ECBC-TR-1426. http://www.dtic.mil/dtic/tr/fulltext/u2/1034269.pdf
9. Rastogi V, Smith L, Angelini D, Harris J, Burton L, Rastogi P, Hurst S, Williams K. Evaluation of commercial off-the-shelf solutions for supporting viability retention of Yersinia pestis cells. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States. 2017; ECBC-TR-1435. http://www.dtic.mil/dtic/tr/fulltext/u2/1041937.pdf
10. Shea AA, Bernhards RC, Cote CK, Chase CJ, Koehler JW, Klimko CP, Ladner JT, Rozak DA, Wolcott MJ, Fetterer DP, Kern SJ, Koroleva GI, Lovett SP, Palacios GF, Toothman RG, Bozue, JA, Worsham PL, Welkos SL. Two stable variants of Burkholderia pseudomallei strain MSHR5848 express broadly divergent in vitro phenotypes associated with their virulence differences. PLoS ONE. 2017 Feb 10; 12(2). doi: 10.1371/journal.pone.0171363. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0171363
11. Zohdi TI, Cabalo J. On the thermomechanics and footprint of fragmenting blasts. Int J of Eng Sci. 2017 Sep; 118:28-39. doi: 10.1016/j.ijengsci.2017.05.007. http://www.sciencedirect.com/science/article/pii/S0020722517310844

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms (including viruses and prions) and or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: Development of non-medical defensive material against biological agents including: research, development, and engineering for methods of rapid detection, identification, decontamination, and physical protection from biological threat agents. Additional information is available at http://www.ecbc.army.mil/research/index.html.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens, Simulants

Outdoor Studies: None

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?
2900 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	315 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	315 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	9

(ii) **Division of personnel:**

Military	0
Civilian	9

(iii) **Division of personnel by category:**

Scientists	2
Engineers	0
Technicians	7
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**
Biochemistry, Molecular Biology, Pharmacology, Physiology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
Yes. Number: 5

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Defense (DoD) – wholly

(vii) **What are the funding levels for the following program areas:**

Research	\$ 273,000
Development	\$ 0
Test and evaluation	\$ 0
Total	\$ 273,000

(viii) **Briefly describe the publication policy of the facility:**
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 “Standards for Technical Reporting”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 “The Army Public Affairs Program”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 “Operations Security”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Beske, PH, Hoffman, KM, Machamer, JB, Eisen, MR, McNutt, PM. Use-dependent potentiation of voltage-gated calcium channels rescues neurotransmission in nerve terminals intoxicated by botulinum neurotoxin serotype A. Scientific Reports. 2017 Nov; 7(1): 15862. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5696531/
2. Beske PH, Bradford AB, Hoffman KM, Mason, S, McNutt, PM. In vitro and ex vivo screening of candidate therapeutics to restore neurotransmission in nerve terminals intoxicated by botulinum neurotoxin serotype A1. Toxicon. 2017 Oct 17. [Epub ahead of print]. http://www.sciencedirect.com/science/article/pii/S0041010117303148?via%3Dihub
3. Jacobson AR, Adler M, Silvaggi NR, Allen KN, Smith GM, Fredenburg RA, Stein RL, Park JB, Feng X, Shoemaker CB, Deshpande SS, Goodnough MC, Malizio CJ, Johnson EA, Pellett S, Tepp WH, Tzipori S. Small molecule metalloprotease inhibitor with in vitro, ex vivo and in vivo efficacy against botulinum neurotoxin serotype A. Toxicon. 2017 June; 137: 36-47. http://www.sciencedirect.com/science/article/pii/S0041010117302052?via%3Dihub
4. Vazquez-Cintron EJ, Beske PH., Tenezaca L, Tran BQ, Oyler JM, Glotfelty EJ, Angeles CA, Syngkon A, Mukherjee J, Kalb SR, Band PA, McNutt PM, Shoemaker CB, Ichtchenko K. Engineering botulinum neurotoxin C1 as a molecular vehicle for intra-neuronal drug delivery. Scientific Reports. 2017 Feb 21; 7: 42923. doi: 10.1038/srep42923. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5318933/

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[7] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Discover and develop medical products and knowledge solutions against toxin threats through research, education and training, and consultation. USAMRICD performs comprehensive, basic scientific research using established and emerging technologies that support the transition of products to advanced development; develops education and training capabilities for military, interagency, domestic, and international personnel in the medical management of chemical casualties; and provides a venue for mutually beneficial collaboration with external investigators and interagency partners to conduct medical chemical defense research against chemical warfare agents and toxins. See more at: http://usamricd.apgea.army.mil/

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[7] Including viruses and prions.

Microorganisms and/or Toxins Studied: HHS Select Toxins

Outdoor Studies: None

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

2. Where is it located (provide both address and geographical location)?
1425 Porter Street, Fort Detrick, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	26,026 m^2
BSL-3:	3,139 m^2
BSL-4:	1,186 m^2
Total laboratory floor area:	30,351 m2

4. The organizational structure of each facility:

(i)	**Total number of personnel**	912
(ii)	**Division of personnel:**	
	Military	202
	Civilian	710
(iii)	**Division of personnel by category:**	
	Scientists	266
	Engineers	7
	Technicians	358
	Administrative and support staff	281

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Biochemistry, Chemistry, Clinical Immunology, Entomology, Genetics, Immunology, Microbiology, Molecular Biology, Toxicology, Veterinary Medicine, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 471

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Defense (DoD) – Partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

(vii) What are the funding levels for the following programme areas:

Research	$ 1,980,000
Development	$ 50,500,000*
Test and evaluation	$ 15,400,000
Total	$ 67,880,000

*Includes reimbursables from Cooperative Research and Development Agreements and other Departments, which cannot be differentiated by the above categories.

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)

1. Akhvlediani T, Bautista CT, Garuchava N, Sanodze L, Kokaia N, Malania L, Chitadze N, Sidamonidze K, Rivard RG, Hepburn MJ, Nikolich MP, Imnadze P, Trapaidze N. Epidemiological and Clinical Features of Brucellosis in the Country of Georgia.. PLoS One. 2017 Jan 20; 12(1). [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5249056/
2. Aliota MT, Bassit L, Bradrick SS, Cox B, Garcia-Blanco MA, Gavegnano C, Friedrich TC, Golos TG, Griffin DE, Haddow AD, Kallas EG, Kitron U, Lecuit M, Magnani DM, Marrs C, Mercer N, McSweegan E, Ng LFP, O'Connor DH, Osorio JE, Ribeiro GS, Ricciardi M, Rossi SL, Saade G, Schinazi RF, Schott-Lerner GO, Shan C, Shi PY, Watkins DI, Vasilakis N, Weaver SC. Zika in the Americas, year 2: What have we learned? What gaps remain? A report from the Global Virus Network. Antiviral Res. 2017 Aug; 144:223-246. http://www.sciencedirect.com/science/article/pii/S016635421730400X?via%3Dihub
3. Amarasinghe GK., Bao YM, Basler CF, Bavari S, Beer M, Bejerman N, Blasdell KR, Bochnowski A, Briese T, Bukreyev A, C. Calisher CH, Chandran K, Collins PL, Dietzgen RG, Dolnik O, Durrwald R, Dye JM, Easton AJ, Ebihara H, Fang Q, Formenty P, Fouchier RAM, Ghedin E, Harding RM, Hewson R, Higgins CM, Hong J, Horie M, James AP, Jiang DH, Kobinger GP, Kondo H, Kurath G, Lamb RA, Lee B, Leroy EM, Li

M, Maisner A, Muhlberger E, Netesov SV, Nowotny N, Patterson JL, Payne SL, Paweska JT, Pearson MN, Randall RE, Revill PA, Rima BK, Rota P, Rubbenstroth D, Schwemmle M, Smither SJ, Song QS, Stone DM, Takada A, Terregino C, Tesh RB, Tomonaga K, Tordo N, Towner JS, Vasilakis N, Volchkov VE, Wahl-Jensen V, Walker PJ, Wang BB, Wang D, Wang F, Wang LF, Werren JH, Whitfield AE, Yan ZC, Ye GY, Kuhn JH. Taxonomy of the order Mononegavirales: update. Arch Virol. 2017 April; 162(8):2493-2504. https://www.ncbi.nlm.nih.gov/pubmed/28389807

4. Bao YM., Amarasinghe GK, Basler CF, Bavari S, Bukreyev A, Chandran K, Dolnik O, M. Dye, H. Ebihara, P. Formenty, R. Hewson, G. P. Kobinger, E. M. Leroy, E. Muhlberger J, Netesov SV, Patterson JL, Paweska JT, Smither SJ, Takada A, Towner JS, Volchkov VE, Wahl-Jensen V, Kuhn JH. Implementation of Objective PASC-Derived Taxon Demarcation Criteria for Official Classification of Filoviruses. Viruses. 2017 May 11; 9(5): 106. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5454419/
5. Bearss JJ, Hunter M, Dankmeyer JL, Fritts KA, Klimko CP, Weaver CH, Shoe JL, Quirk AV, Toothman RG, Webster WM, Fetterer DP, Bozue JA, Worsham PL, Welkos SL, Amemiya K, Cote CK. Characterization of pathogenesis of and immune response to Burkholderia pseudomallei K96243 using both inhalational and intraperitoneal infection models in BALB/c and C57BL/6 mice. PLoS One. 2017 Feb 24; 12(2). [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5325312/
6. Bekerman E, Neveu G, Shulla A, Brannan J, Pu SY, Wang S, Xiao F, Barouch-Bentov R, Bakken RR, Mateo R, Govero J, Nagamine CM, Diamond MS, De Jonghe S, Herdewijn P, Dye JM, Randall G, Einav S. Anticancer kinase inhibitors impair intracellular viral trafficking and exert broad-spectrum antiviral effects. J Clin Invest. 2017 Feb 27; 127(4):1338-1352. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373883/
7. Bell TM, Shaia CI, Bearss JJ, Mattix ME, Koistinen KA, Honnold SP, Zeng X, Blancett CD, Donnelly GC, Shamblin JD, Wilkinson ER, Cashman KA. Temporal Progression of Lesions in Guinea Pigs Infected With Lassa Virus. Veterinary Pathology; 2017 May 1; 54(3):549-562. http://journals.sagepub.com/doi/full/10.1177/0300985816677153
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9. Bowen LE, Bailey MM, Haupt BR, Anderson JB. Development and characterization of an oro-nasal inhalation plethysmography mask exposure system. Aerosol Sci Technol. 2017 Jan 17; 51(4):509-517. http://www.tandfonline.com/doi/abs/10.1080/02786826.2016.1274824?journalCode=uast20
10. Brown JF, Rowe K, Zacharias P, Van Hasselt J, Dye JM, Wohl DA, Fischer WA, Cunningham CK, Thielman NM, and Hoover DL. Apheresis for collection of Ebola convalescent plasma in Liberia. Journal of Clinical Apheresis. 2017 June; 32(3):175-181. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5580942/
11. Burnouf T, Dye JM, Abayomi A. Convalescent Plasma and the Dose of Ebola Virus Antibodies. N Engl J Med. 2017 March; 376(13):1296-1297. http://www.nejm.org/doi/full/10.1056/NEJMc1700090

12. Caviness K, Kuhn JH, and Palacios G. Ebola virus persistence as a new focus in clinical research. Curr Opin Virol. 2017 Apr; 23:43-48. http://www.sciencedirect.com/science/article/pii/S187962571630205X
13. Chance T, Chua J, Toothman RG, Ladner JT, Nuss JE, Raymond JL, Biot FV, Demons S, Miller L, Halasohoris S, Mou S, Koroleva G, Lovett S, Palacios G, Vietri NJ, Worsham PL, Cote CK, Kijek TM, Bozue JA. A spontaneous mutation in kdsD, a biosynthesis gene for 3 Deoxy-D-manno-Octulosonic Acid, occurred in a ciprofloxacin resistant strain of Francisella tularensis and caused a high level of attenuation in murine models of tularemia. PLoS One; 2017 March; 12(3). [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5362203/
14. Chaudhury S, Regules JA, Darko CA, Dutta S, Wallqvist A, Waters NC, E. Jongert E, Lemiale F, Bergmann-Leitner ES. Delayed fractional dose regimen of the RTS, S/AS01 malaria vaccine candidate enhances an IgG4 response that inhibits serum opsonophagocytosis. Sci Rep. 2017 Aug 11; 7:7998. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5554171/
15. Cooper CL, Martins KA, Stronsky SM, Langan DP, Steffens J, Van Tongeren S, Bavari S. T-cell-dependent mechanisms promote Ebola VLP-induced antibody responses, but are dispensable for vaccine-mediated protection. Emerg Microbes Infect. 2017 Jun; 6(6). [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5520308/
16. Costa-da-Silva AL, Ioshino RS, Petersen V, Lima AF, Cunha MDP, Wiley MR, Ladner JT, Prieto K, Palacios G, Costa DD, Suesdek L, de Andrade Zanotto PM, Capurro ML. First report of naturally infected Aedes aegypti with chikungunya virus genotype ECSA in the Americas. PLoS Negl Trop Dis. 2017 Jun; 11(6). [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5470658/
17. Dudas G, Carvalho LM, Bedford T, Tatem AJ, Baele G, Faria NR, Park DJ, Ladner JT, Arias A, Asogun D, Bielejec F, Caddy SL, Cotton M, D'Ambrozio J, Dellicour S, Di Caro A, Diclaro JW, Duraffour S, Elmore MJ, Fakole LS, Faye O, Gilbert ML, Gevao SM, Gire S, Gladden-Young A, Gnirke A, Goba A, Grant DS, Haagmans BL, Hiscox JA, Jah U, Kugelman JR, Liu D, Lu J, Malboeuf CM, Mate S, Matthews DA, Matranga CB, Meredith LW, Qu J, Quick J, Pas SD, Phan MVT, Pollakis G, Reusken CB, Sanchez-Lockhart M, Schaffner SF, Schieffelin JS, Sealfon RS, Simon-Loriere E, Smits SL, Stoecker K, Thorne L, Tobin EA, Vandi MA, Watson SJ, West K, Whitmer S, Wiley MR, Winnicki SM, Wohl S, Wolfel R, Yozwiak NL, Andersen KG, Blyden SO, Bolay F, Carroll MW, Dahn B, Diallo B, Formenty P, Fraser C, Gao GF, Garry RF, Goodfellow I, Gunther S, Happi CT, Holmes EC, Kargbo B, Keita S, Kellam P, Koopmans MPG, Kuhn JH, Loman NJ, Magassouba N, Naidoo D, Nichol ST, Nyenswah T, Palacios G, Pybus OG, Sabeti PC, Sall A, Stroher U, Wurie I, Suchard MA, Lemey P, Rambaut A. Virus genomes reveal factors that spread and sustained the Ebola epidemic. Nature. 2017 Apr 20; 544 (7650):309-315. https://www.nature.com/articles/nature22040?foxtrotcallback=true
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Develop medical countermeasures, including candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents, and to perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at http://www.usamriid.army.mil/.

Agents Microorganisms and/or Toxins: Select Agents (HHS, Overlap) and Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: None

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[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Air Force Research Laboratory, 711 Human Performance Wing (HPW), United States Air Force School of Aerospace Medicine (USAFSAM)

2. Where is it located (provide both address and geographical location)?
2510 Fifth Street, Building 840, Wright Patterson AFB, Ohio 454336

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	210 m^2
BSL-3:	60 m^2
BSL-4:	0 m^2
Total laboratory floor area:	270 m^2

4. The organizational structure of each facility:

(x)	**Total number of personnel:**	3

(xi) **Division of personnel:**

Military	0
Civilian	3

(xii) **Division of personnel by category:**

Scientists	2
Engineers	0
Technicians	1
Administrative and support staff	0

(xiii) **List the scientific disciplines represented in the scientific/engineering staff:**
Microbiology, Molecular Biology

(xiv) **Are contractor staff working in the facility? If so, provide an approximate number:**
No

(xv) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Defense (DoD) – wholly

(xvi) **What are the funding levels for the following program areas:**

Research	$ 0
Development	$ 0
Test and evaluation	$ 100,000
Total	$ 100,000

(xvii) Briefly describe the publication policy of the facility:

The 711 HPW Policy: Documents, including journal articles, presentations, and technical reports for Public Release (e.g., peer reviewed journals) and Limited Release (e.g., DITC) are submitted to 711 HPW STINFO and OPSEC/Public Affairs review and approval before publication.

(xviii) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):
None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[8] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Provide capabilities for the diagnostic techniques and detection of bacterial biological select agent and novel threats.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens.

Outdoor Studies: None

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[8] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

US Army Natick Soldier Research Development and Engineering Center (NSRDEC)

2. Where is it located (provide both address and geographical location)?

15 General Greene Avenue, Natick, MA 01760

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	68 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	68 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 1

(ii) Division of personnel:

Military	0
Civilian	1

(iii) Division of personnel by category:

Scientists	1
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Microbiology

(v) Are contractor staff working in the facility? If so, provide an approximate number:

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 30,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 30,000

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 “Standards for Technical Reporting”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 “The Army Public Affairs Program”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 “Operations Security”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)
None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: NSRDEC is chartered with developing technologies in the areas of individual soldier protection, combat ration development, air drop systems, and shelters. Additional information is available at https://www.nsrdec.army.mil/#/.

Agents Microorganisms and/or Toxins: Simulant

Outdoor Studies: None

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[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Brookhaven National Laboratory

2. Where is it located (provide both address and geographical location)?

Brookhaven National Laboratory, Biology Department
Brookhaven Ave, Upton, New York 11973
(Located on William Floyd Parkway, County Road 46, 1.5 miles north of Long Island Expressway Exit 68)

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	18 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	18 m^2

4. The organizational structure of each facility:

(i) **Total number of personnel:** 1

(ii) **Division of personnel:**

Military	0
Civilian	1

(iii) **Division of personnel by category:**

Scientists	1
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Structural Biology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) – wholly

(vii) **What are the funding levels for the following program areas:**

Research	$ 33,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 33,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy facility, BNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. BNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. BNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[9] and/or toxins studied, as well as outdoor studies of biological aerosols:

***Objectives*:** The overall objective of the work is to develop countermeasures for biowarfare agents. The specific aims of the projects are to determine the three-dimensional structures of the agents. The purified agents are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Source (also located at Brookhaven National Laboratory) for x-ray diffraction studies. These results can lead to vaccine development, treatment, and/or diagnosis and detection.

***Microorganisms and/or Toxins Studied*:** HHS Select Toxin

***Outdoor Studies*:** None.

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[9] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Lawrence Livermore National Laboratory (LLNL)

2. Where is it located (provide both address and geographical location)?

7000 East Avenue, Livermore, California 94550
(62 km east-southeast of San Francisco, California)

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,820.4 m^2
BSL-3:	59.5 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,879.9 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 57

(ii) Division of personnel:

Military:	0
Civilian:	57

(iii) Division of personnel by category:

Scientists	17
Engineers	16
Technicians	15
Administrative and support staff	9

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Biomedical Engineering, Biomedical Science, Biotechnology, Computational Biology, Computer Science, Environmental Science, Epidemiology, Genomics, Immunology, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Proteomics, Toxinology, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DoD) – partially
U.S. Department of Energy (DOE)
U.S. Department of Health & Human Services (HHS)
U.S. Department of Homeland Security (DHS)

(vii) What are the funding levels for the following program areas:

Research	$ 3,913,000
Development	$ 3,951,000

Test and evaluation	$ 1,317,000
Total	$ 9,181,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy facility, LLNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LLNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LLNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Renner LD, Zan J, Hu LI, Martinez M, Resto PJ. Detection of ESKAPE Bacterial Pathogens at the Point of Care Using Isothermal DNA-Based Assays in a Portable Degas-Actuated Microfluidic Diagnostic Assay Platform. Appl Environ Microbiol. 2017 Feb 15; 83(4):e02449-16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5288812/
2. Serre S, Mickelsen L, Calfee W, Gray M, Kern B. Subway Railcar Decontamination with Methyl Bromide - Decontamination of a Subway Railcar within Methyl Bromide Fumigant on Bacillus anthracis Sterne Strain Spores, 2017 March. https://www.epa.gov/sites/production/files/2017-04/documents/utr_rolling_stock_fumigation_with_methyl_bromide.pdf
3. Weilhammer D, Dunkle AD, Blanchette CD, Fischer NO, Corzett M. Enhancement of antigen-specific CD4$^+$ and CD8$^+$ T cell responses using a self-assembled biologic nanolipoprotein particle vaccine. Vaccine. 2017 Mar 13; 35(11):1475-1481. http://www.sciencedirect.com/science/article/pii/S0264410X17301676?via%3Dihub
4. Gilmore SF, He W, Rasley A, Fischer NO. Strategies for Functionalizing Lipoprotein-Based Nanoparticles. In: Ilies MA editor. Control of Amphiphile Self-Assembling at the Molecular Level: Supra-Molecular Assemblies with Tuned Physicochemical Properties for Delivery Applications. Washington, DC: Oxford University Press; 2017 Nov 15. p 131-150. eISBN: 9780841232730. http://pubs.acs.org/doi/abs/10.1021/bk-2017-1271.ch006
5. Shah S, Kane S, Erler A, Alfaro T. Sample Processing Approach for Detection of Ricin in Surface Samples. J Immunol Meth. 2017 Dec; 451:54-60. http://www.sciencedirect.com/science/article/pii/S002217591730203X?via%3Dihub
6. Jaing C, Rowland R, Allen J, Certoma A, Thissen J. Gene expression analysis of whole blood RNA from pigs infected with low and high pathogenic African swine fever viruses. Sci Rep. 2017 Aug 31; 7:10115. https://www.nature.com/articles/s41598-017-10186-4
7. Schmid MA, González KN, Shah S, Peña J, Mack M. Influenza and dengue virus co-infection impairs monocyte recruitment to the lung, increases dengue virus titers, and exacerbates

pneumonia. Eur J Immunol. 2017 Mar; 47(3):527-539. http://onlinelibrary.wiley.com/doi/10.1002/eji.201646675/epdf

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[10] and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives**:** The biological defense research conducted at Lawrence Livermore National Laboratory includes biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, assay development for monitoring for biological decontamination/response as well as microbial forensic assay development to help determine geographic origin and attribution. LLNL also works to develop diagnostic platforms that use a variety of techniques, such as polymerase chain reaction (PCR), immunoassay, microarray, mass spectrometry and genomic sequencing used to gather useful information about the species present in the sampling environment. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions. Additional information is available at https://st.llnl.gov/ .

Microorganisms and/or Toxins Studied**:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens

Outdoor Studies**:** None.

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[10] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Los Alamos National Laboratory (LANL)

2. Where is it located (provide both address and geographical location)?

Bikini Atoll Road SM-30, Los Alamos, NM 87545
(Approximately 45 miles west of Santa Fe, New Mexico)

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	403.6 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	403.6 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	20

(ii) Division of personnel:

Military	0
Civilian	20

(iii) Division of personnel by category:

Scientists	9
Engineers	0
Technicians	11
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Analytical Biochemistry, Analytical Chemistry, Bacteriology, Bioinformatics, Biological Science, Biomedical Engineering, Biomedical Science, Cell Biology, Ecology, Environmental Science, Genetics, Genomics, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Plant Molecular Biology, Proteomics, Public Health, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DoD) – partially
U.S. Department of Health & Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
U.S. Agency for International Development (USAID)

(vii) What are the funding levels for the following program areas:

Research	$6,345,000
Development	$2,000,000
Test and evaluation	$2,900,000

Total	$11,245,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy facility, LANL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LANL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LANL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Halpin JL, Hill K, Johnson SL, et al. Finished Whole-Genome Sequence of *Clostridium argentinense* Producing Botulinum Neurotoxin Type G. Genome Announc. 2017 May 25; 5(21):e00380-17. http://genomea.asm.org/content/5/21/e00380-17.abstract.
2. Halpin JL, Hill K, Johnson SL, et al. Finished Whole-Genome Sequences of *Clostridium butyricum* Toxin Subtype E4 and *Clostridium baratii* Toxin Subtype F7 Strains. Genome Announc. 2017 Jul 20; 5(29): e00375-17. http://genomea.asm.org/content/5/29/e00375-17.abstract.
3. Halpin JL, Hill K, Johnson SL, et al. Finished Whole-Genome Sequences of Two *Clostridium botulinum* Type A(B) Isolates. Genome Announc. 2017 May 25; 5(21):e00381-17. http://genomea.asm.org/content/5/21/e00381-17.abstract.
4. Khmaladze E, Dzavashvili G, Chanturia G, et al. Ten Genome Sequences of Human and Livestock Isolates of *Bacillus anthracis* from the Country of Georgia. Genome Announc. 2017 May 11; 5(19):e00256-17. http://genomea.asm.org/content/5/19/e00256-17.abstract.
5. Kubicek-Sutherland JZ, Vu DM, Mendez HM, Jakhar S, Mukundan H. Detection of Lipid and Amphiphilic Biomarkers for Disease Diagnostics. Biosen. 2017 Jul 4; 7(3):E25. http://www.mdpi.com/2079-6374/7/3/25.
6. Stromberg LR, Mendez HM, Mukundan H. Detection Methods for Lipopolysaccharides: Past and Present. In: Samie A, editor. *Escherichia coli* - Recent Advances on Physiology, Pathogenesis and Biotechnological Applications: InTech; 2017. p. 141-68. https://www.intechopen.com/books/-i-escherichia-coli-i-recent-advances-on-physiology-pathogenesis-and-biotechnological-applications/detection-methods-for-lipopolysaccharides-past-and-present.
7. Vu DM, Sakamuri RM, Waters WR, Swanson BI, Mukundan H. Detection of Lipomannan in Cattle Infected with Bovine Tuberculosis. Analyt Sci. 2017; 33(4):457-60. https://www.jstage.jst.go.jp/article/analsci/33/4/33_457/_article.
8. Xie G, Johnson SL, Davenport KW, et al. Exception to the Rule: Genomic Characterization of Naturally Occurring Unusual *Vibrio cholerae* Strains with a Single Chromosome. Int J Genomics. 2017 Aug 29;. https://doi.org/10.1155/2017/8724304.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[11] and/or toxins studied, as well as outdoor studies of biological aerosols:

***Objectives*:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection, integrative biosurveillance and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interaction; study molecular, chemical, and physical characteristics of biothreat agents, including bacteria, viruses and toxins, for detection, characterization, assay design and improvement; evaluate detection assay and platform performance; assess commercial techniques for pathogen detection and biosurveillance on environmental monitoring procedures; develop DNA, RNA and protein based bioforensics assays; develop next generation high throughput microbial sequencing, finishing and analysis capabilities; perform viral and bacterial pathogen sequencing for characterization, comparative genomic analysis, and metagenomic analysis; develop high throughput assays for host-pathogen protein interactions screening; develop and validate assays to improve the ability to identify and characterize bioterrorism incident; and identify host molecular targets as potential therapeutic candidates. Additional information is available at http://www.lanl.gov/org/padste/adcles/bioscience/biosecurity-public-health/index.php

***Microorganisms and/or Toxins Studied*:**
None

***Outdoor Studies*:** None.

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[11] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Pacific Northwest National Laboratory (PNNL)

2. Where is it located (provide both address and geographical location)?

902 Battelle Boulevard, Richland, Washington 99352
Located 146 miles southwest from Spokane, WA and 203 miles southeast from Seattle, WA.

* The PNNL has two campuses, located in both Richland and Sequim, in Washington State. In a change from previous years, this 2017 CBM entry for PNNL includes information on only the facility located in Richland, WA, as no reportable activities took place at the facility in Sequim, WA during 2017.

3. Floor area of laboratory areas by containment level (m^2):

BSL-2	650 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area:	650 m^2

4. The organizational structure of each facility:

(i) Total number of personnel:	84

(ii) Division of personnel:

Military	0
Civilian	84

(iii) Division of personnel by category:

Scientists	71
Engineers	1
Technicians	0
Admin and Support Staff	12

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science, Cell Biology, Chemistry, Computational Biology, Genetics, Genomics, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Pathology, Proteomics, Structural Biology, Systems Biology, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DoD) – partially
U.S. Department of Energy (DOE)
U.S. Department of Health & Human Services (HHS)
U.S. Department of Homeland Security (DHS)

Internal (Laboratory Directed Research and Development)
Other Government Agencies

(vii) What are the funding levels for the following program areas:

Research	$10,261,000
Development	$265,000
Test and evaluation	$1,425,000
Total	$11,951,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy, Office of Science facility, PNNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. PNNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. PNNL also has procedures in place to manage and protect classified, controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view] For this location, a searchable database of materials published since 1988 is available at http://www.pnnl.gov/publications/

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Burnum-Johnson KE, Kyle JE, Eisfeld AJ, et al MPLEx: A method for simultaneous pathogen inactivation and extraction of samples for multi-omics profiling. Analyst. 2017 Jan 10; 142(3):442-448. http://pubs.rsc.org/en/content/articlepdf/2017/an/c6an02486f
2. Kyle JE, Crowell KL, Casey CP, et al. LIQUID: an-open source software for identifying lipids in LC-MS/MS-based lipidomics data. Bioinformatics. 2017 Jun 1; 33(11):1744-1746. https://academic.oup.com/bioinformatics/article/33/11/1744/2964726
3. Eisfeld AJ, Halfmann PJ, Wendler JP, et al. Multi-platform 'Omics Analysis of Human Ebola Virus Disease Pathogenesis. Cell Host & Microbe. 2017 Dec 13; 22(6):817-829. http://www.sciencedirect.com/science/article/pii/S1931312817304468?via%3Dihub
4. Kyle JE, Casey CP, Stratton KG, et al. Comparing Identified and Statistically Significant Lipids and Metabolites in 15-Year Old Serum and Dried Blood Spot Samples for Longitudinal Studies. Rapid Comm Mass Spec. 2017 Nov 16; 31(5):447-456. http://onlinelibrary.wiley.com/doi/10.1002/rcm.7808/epdf
5. Zheng X, Wojcik R, Zhang X, et al. Coupling Front-end Separations, Ion Mobility Spectrometry, and Mass Spectrometry for Enhanced Multidimensional Biological and Environmental Analyses. Ann Rev Analy Chem. 2017 Feb 23; 10(1):71-92. http://www.annualreviews.org/doi/pdf/10.1146/annurev-anchem-061516-045212
6. Menachery VD, Mitchell HD, Cockrell AS, et al. MERS-CoV Accessory ORFs play key role for infection and pathogenesis. mBio. 2017 Aug 22; 8(4): e00665-17.

http://mbio.asm.org/content/8/4/e00665-17.short?rss=1&cited-by=yes&legid=mbio;8/4/e00665-17

7. Menachery VD, Gralinski LE, Mitchell HD, et al. Middle East Respiratory Syndrome Coronavirus Nonstructural Protein 16 is Necessary for Interferon Resistance and Viral Pathogenesis. mSphere. 2017 Nov 15; 2(6): e00346-17. http://msphere.asm.org/content/msph/2/6/e00346-17.full.pdf
8. Negretti NM, Gourley CR, Clair GCD, et al. The food-borne pathogen *Campylobacter jejuni* responds to the bile salt deoxycholate with countermeasures to reactive oxygen species. Scientific Reports. 2017 Nov 13; 7(1):15455. https://www.nature.com/articles/s41598-017-15379-5.pdf
9. Buchko GW, Echols N, Flynn EM, et al. Structural and biophysical characterization of the *Mycobacterium tuberculosis* protein Rv0577, a protein associated with neutral red staining of virulent tuberculosis strains and homologue of the *Streptomyces coelicolor* protein KbpA. Biochemistry. 2017 Jul 10; 56(30):4015-4027. http://pubs.acs.org/doi/pdf/10.1021/acs.biochem.7b00511
10. Buchko GW, Clifton MC, Wallace E, Atkins KA, Myler PJ. Backbone chemical shift assignments and secondary structure analysis of the U1 protein from the *Bas-Congo virus*. Biomolecular NMR Assignments. 2017 Apr; 11(1):51-56. https://www.ncbi.nlm.nih.gov/pubmed/27981424
11. Roberto FF, Arce JS, Beck LC, et al. AOAC SMPR 2016.009 Standard Method Performance Requirements (SMPRs) for DNA-Based Methods of Detecting *Brucella suis* in Field-Deployable, Department of Defense Aerosol Collection Devices. J AOAC Int. 2017 Jan 1; 100(1):255-260. https://nau.pure.elsevier.com/en/publications/aoac-smpr-2016009-standard-method-performance-requirements-smprs-
12. Gee J, Arce JS, Beck LC, et al. AOAC SMPR 2016.010 Standard Method Performance Requirements (SMPRs) for DNA-Based Methods of Detecting *Burkholderia pseudomallei* in Field-Deployable, Department of Defense Aerosol Collection Devices. J AOAC Int. 2017 Jan 1; 100(1):261-265. http://www.ingentaconnect.com/content/aoac/jaoac/2017/00000100/00000001/art00034;jsessionid=1q23i0nwc2fjg.x-ic-live-03
13. Sharma S, Arce JS, Beck LC, et al. AOAC SMPR 2016.011 Standard Method Performance Requirements (SMPRs) for Detection of Botulinum Neurotoxins A1 and A2 in Field-Deployable, Department of Defense Aerosol Collection Devices. J AOAC Int. 2017 Jan 1; 100(1):266-269. http://www.ingentaconnect.com/content/aoac/jaoac/2017/00000100/00000001/art00035
14. Ozanich RM, Colburn HA, Victry KD, et al. Evaluation of PCR Systems for Field Screening of *Bacillus anthracis*. Health Security. 2017 Feb 1; 15(1):70-80. http://online.liebertpub.com/doi/10.1089/hs.2016.0043
15. Bartholomew RA, Ozanich RM, Arce JS, et al. Evaluation of Immunoassays and General Biological Indicator Tests for Field Screening of *Bacillus anthracis* and Ricin. Health Security. 2017 Feb 1; 15(1):81-96. http://online.liebertpub.com/doi/abs/10.1089/hs.2016.0044
16. Ozanich RM, Bartholomew RA, Bruckner-Lea CJ. Response to Letter on Immunoassays for Field Screening of *Bacillus anthracis* and Ricin. Health Security. 2017 Apr 1; 15(2):222. http://online.liebertpub.com/doi/abs/10.1089/hs.2017.0011.resp?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed
17. Volkova S, Charles-Smith LE, Harrison JJ, Corley CD. Uncovering the Relationships Between Military Community Health and Affects Expressed in Social Media. EPJ Data Science. 2017 Jun 8; 6(1):9. https://epjdatascience.springeropen.com/articles/10.1140/epjds/s13688-017-0102-z

18. Turner MW, Cort JR, Mcdougal OM. α-Conotoxin Decontamination Protocol Evaluation: What Works and What Doesn't. Toxins. 2017 Sep 14; 9(9):281. http://www.mdpi.com/2072-6651/9/9/281
19. Merkley ED, Jenson SC, Arce JS, et al. Ricin-Like Proteins from the Castor Plant Do Not Influence Liquid Chromatography-Mass Spectrometry Detection of Ricin in Forensically Relevant Samples. Toxicon. 2017 Dec 15; 140:18-31. https://www.sciencedirect.com/science/article/pii/S004101011730301X?via%3Dihub

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[12] and/or toxins studied, as well as outdoor studies of biological aerosols:

***Objectives*:** PNNL is involved in biodefense-related activities, to include: agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of detection methods (e.g., nucleic acid, toxin, and proteomic signatures), testing and evaluation of commercial off the shelf equipment for agent detection as well as investigation of next generation biodetection equipment, biological and chemical forensics, investigation of natural history of agents, pathogenesis studies, and interrogating DNA sequencing data and related analysis tools. No outdoor studies of biological aerosols were collected.

***Microorganisms and/or toxins studied*:** Select Agents (HHS, Overlap), NIAID Category A, Simulants

***Outdoor Studies*:** None.

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[12] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Sandia National Laboratories (SNL)

2. Where is it located (provide both address and geographical location)?

New Mexico Campus: P. O. Box 5800, Albuquerque, NM 87185
(Located on Kirtland Air Force Base, in southeastern Albuquerque)

California Campus: 7011 East Avenue, Livermore, California
(Located in Livermore, CA)

[Note: Personnel and budget are shared between New Mexico and California campuses.]

3. Floor area of laboratory areas by containment level (m^2):

New Mexico campus:

BSL-2:	1242.20 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1242.20 m^2

California campus:

BSL-2:	230 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	230 m^2

4. The organizational structure of each facility:

(i) Total number of personnel:

New Mexico campus:	158
California campus:	77

(ii) Division of personnel:

Military	0
Civilian	235

(iii) Division of personnel by category:

Scientists	105
Engineers	27
Technicians	78
Admin and Support Staff	25

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Aerosol Science, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Materials Science, Medicine, Nanotechnology, Aerobiology, Bioinformatics, Biological Science, Cell Biology, Immunology, Molecular Biology, Virology, Molecular Diagnostics, Biophysics, Chemistry, Physics, Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Bacteriology, Bioinorganic Chemistry, Biomedical Science, Computational Biology, Computer Engineering, Computer Science, Electrical Engineering, Environmental

Engineering, Environmental Science, Genetics, Genomics, Mass Spectrometry, Mathematics, Mechanical Engineering, Microbial Forensics, Microbiology, Neuroscience, Operations Research Analysis, Optical Spectroscopy, Pathology, Physiology, Polymer Science, Protein Engineering, Proteomics, Structural Biology, Toxicology.

(v) Are Contractor staff working in the facility?
No

(vi) What is (are) the source(s) of funding for the work conducted in the facility?
Department of Defense (DoD) - partially
Department of Health and Human Services (HHS)
Department of Homeland Security (DHS)
Internal (Laboratory Directed Research & Development)
Private sector

(vii) What are the funding levels for Research and Development and Testing and Evaluation as of the most recent calendar year?

Research	$ 9,948,159.75
Development	$ 893,571.79
Test and Evaluation	$ 5,539,968.00
Total	$ 16,381,699.54

(viii) Briefly describe the publication policy of the facility:
As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Sandia National Laboratories is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. SNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. SNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly available papers and reports resulting from work during the previous 12 months:

1. Eid C, Branda SS, Meagher RJ. A Rapidly-Prototyped Microfluidic Device for Size-Based Nucleic Acid Fractionation Using Isotachophoresis. Analyst. 2017 Jun. 142(12): 2094-99. http://dx.doi.org/10.1039/c7an00431a.
2. Gach PC, Iwai K, Kim PW, Hillson NJ, Singh AK. Droplet Microfluidics for Synthetic Biology. Lab on a Chip. 2017 Aug 10. 17:3388-400. http://dx.doi.org/10.1039/c7lc00576h.
3. Graus MS, Neumann AK, Timlin JA. Hyperspectral Fluorescence Microscopy Detects Autofluorescent Factors That Can Be Exploited as a Diagnostic Method for *Candida* Species

Differentiation. J Biomed Opt. 2017 Jan 1. 22(1):16002.
http://dx.doi.org/10.1117/1.jbo.22.1.016002

4. Ma P, Cardenas AE, Chaudhari MA, Elber R, Rempe SB. The Impact of Protonation on Early Translocation of Anthrax Lethal Factor: Kinetics from Molecular Dynamics Simulations and Milestoning Theory. J ACS. 2017 Oct 11. 139(42):14837-40. http://dx.doi.org/10.1021/jacs.7b07419
5. McBride AA, Price DN, Muttil P. Preparation and Characterization of Magnetic Nano-in-Microparticles for Pulmonary Delivery. Methods Mol Biol. 2017 Feb 02. 1530:99-108. http://dx.doi.org/10.1007/978-1-4939-6646-2_5.
6. Priye A, Bird SW, Light YK, et al. A Smartphone-Based Diagnostic Platform for Rapid Detection of Zika, Chikungunya, and Dengue Viruses. Sci Rep. 2017 Mar 20. 7:44778. http://dx.doi.org/10.1038/srep44778.
7. Sissoko D, Keita M, Diallo B, et al. Ebola Virus Persistence in Breast Milk after No Reported Illness: A Likely Source of Virus Transmission from Mother to Child. Clin Infect Dis. 2017 Feb 15. 64(4): 513-16. http://dx.doi.org/10.1093/cid/ciw793.
8. Vanegas JM, Heinrich F, Rogers DM, et al. Study of Insertion of Dengue E into Lipid Bilayers by Neutron Reflectivity and Molecular Dynamics Simulations. Biophys J. 2017 Feb 3. 112(3): 35A. http://dx.doi.org/10.1016/j.bpj.2016.11.221.

5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: To improve the U.S. ability to anticipate and defend against biological threats, SNL’s multidisciplinary research team is applying its traditional strengths in engineering and technology development to achieve the following goals: 1) Gain basic knowledge regarding the fundamental molecular processes of pathogenesis, including the dynamic interactions between microbial pathogens and their hosts; 2) Develop assays, novel materials, and platforms to detect and diagnose traditional and unknown pathogens, as well as to discover novel therapeutic targets; and 3) Obtain an understanding of the microbiome’s effects on human health in the absence or in the presence of an infectious disease.

Microorganisms and/or toxins studied**:** NIAID Category A

Outdoor studies**:** None

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?

Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Laboratory Services (DLS)

2. Where is it located (include both address and geographical location)?

4770 Buford Highway, Atlanta, Georgia 30341

3. Floor area of laboratory areas by containment level:

BSL-2:	568 m^2
BSL-3:	0 m^2
BSL-4:	0m^2
Total laboratory floor area	568 m^2

4. The organizational structure of each facility.

(i) **Total number of personnel**	18
(ii) **Division of personnel**:	
Military	0
Civilian	18
(iii) **Division of personnel by category**:	
Scientists	18
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Biochemistry, Biology, Chemistry, Mass Spectrometry, Proteomics

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 4

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$1,728,693
Development	$933,000
Test and evaluation	$733,814
Total	$3,395,507

(viii) Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings.

The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. M. Gallegos-Candela, A.E. Boyer, A.R. Woolfitt, J. Brumlow, R.C. Lins, C.P. Quinn, A.R. Hoffmaster, G. Meister, and J.R. Barr, "Validated MALDI-TOF-MS method for anthrax lethal factor provides early diagnosis and evaluation of therapeutics", *Anal Biochem*, **2017**, Dec 7; 543, 97-107. https://www.ncbi.nlm.nih.gov/pubmed/29224733

2. S.R. Kalb, J. Baudys, T.J. Smith, L.A. Smith, and J.R. Barr, "Characterization of Hemagglutinin Negative Botulinum Progenitor Toxins", *Toxins*, **2017**, Jun 15; 9(6), E193. https://www.ncbi.nlm.nih.gov/pubmed/28617306

3. D. Wang, J. Baudys, K.M. Hoyt, J.R. Barr, and S.R. Kalb, "Further Optimization of Peptide Substrate Enhanced Assay Performance for BoNT/A Detection by MALDI-TOF Mass Spectrometry", *Analytical and Bioanalytical Chemistry*, **2017**, Aug; 409(20), 4779-4786. https://www.ncbi.nlm.nih.gov/pubmed/28573317

4. B.Freund, L. Hayes, L. Rivera-Lara, C. Sumner, V. Chaudhry, K. Chatham-Stephens, K. Benedict, S. Kalb, D. Blythe, R. Brooks, and J.C. Probasco, "Adult intestinal colonization botulism mimicking brain death", *Muscle and Nerve*, **2017**, Oct; 56(4), E27-28. http://onlinelibrary.wiley.com/doi/10.1002/mus.25689/full

5. E.J. Vazquez-Cintron, P.H. Beske, B.Q. Tran, J.M. Oyler, E.J. Glotfelty, C.A. Angeles, L. Tenezaca, A. Syngkon, J. Mukherjee, S.R. Kalb, P.A. Band, P.M. McNutt, C.B. Shoemaker, and K. Ichtchenko, "Atoxic Derivative of Botulinum C1 as Molecular Vehicle for Targeted Delivery of Therapeutics to the Neuronal Cytoplasm", *Scientific Reports*, **2017**, Feb 21, 7, 42923. https://www.nature.com/articles/srep42923

6. M.W. Peck, T.J. Smith, F. Anniballi, J.W. Austin, L. Bano, M. Bradshaw, M.P. Cuervo, L.W. Cheng, Y. Derman, B.G. Dorner, A. Fisher, K.K. Hill, S.R. Kalb, H. Korkeala, M. Lindstrom, F. Lista, C. Luquez, C. Mazuet, M. Pirazzini, M.R. Popoff, O. Rossetto, A. Rummel, D. Seasardic, B.R. Singh, and S.C. Stringer, "Historical Perspectives and Guidelines for Botulinum Neurotoxin Subtype Nomenclature, *Toxins*, **2017**, Jan 18, 9(1), E38. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5308270/

7. L. McCrickard, M. Marlow, J. Self, L.F. Watkins, K. Chatham-Stephens, J. Anderson, S. Hand, K. Taylor, J. Hanson, K. Patrick, C. Luquez, J. Dykes, S.R. Kalb, K. Hoyt, J.R. Barr, T. Crawford, A. Chambers, B. Douthit, R. Cox, M. Craig, J. Spurzem, J. Doherty, M. Allswede, P. Byers, and T. Dobbs, "Botulism Outbreak from Drinking Prison-Made Illicit Alcohol in a Federal Correctional Facility—Mississippi, June 2016", *MMWR*, **2017**; 65: 1491-2. https://www.cdc.gov/mmwr/volumes/65/wr/mm6552a8.htm

8. X. Cui, L.D. Nolen, M. Booth, L. Donaldson, C.P. Quinn, A.E. Boyer, K. Hendricks, S. Shadomy, P. Bothma, O. Judd, P. McConnell, W.A. Bower, and P.Q. Eichacker, "Analysis of Anthrax Immune Globulin Intravenous with Antimicrobial Treatment in Injection Drug Users, Scotland, 2009-2010." *Emerg Infect Dis*, **2017**, Jan; 23(1), 56-65. https://www.ncbi.nlm.nih.gov/pubmed/27983504

9. Aakash Shrivastava, Anil Kumar, Jerry D. Thomas, Kayla F Laserson, Gyan Bhushan, Melissa D. Carter, Mala Chhabra, Veena Mittal, Shashi Khare, James J. Sejvar, Mayank Dwivedi, Samantha L. Isenberg, Rudolph Johnson, James L. Pirkle, Jon D. Sharer, Patricia L. Hall, Rajesh Yadav, Anoop Velayudhan, Mohan Papanna, Pankaj Singh, D. Somashekar, Arghya Pradhan, Kapil Goel, Rajesh Pandey, Mohan Kumar, Satish Kumar, Amit Chakrabarti, P. Sivaperumal, A. Ramesh Kumar, Joshua G. Schier, Arthur Chang, Leigh Ann Graham, Thomas P. Mathews, Darryl Johnson, Liza Valentin, Kathleen L. Caldwell, Jeffery M. Jarrett, Leslie A. Harden, Gary R. Takeoka, Suxiang Tong, Krista Queen, Clinton Paden, Anne Whitney, Dana L. Haberling, Ram Singh, Ravi Shankar Singh, Kenneth C. Earhart, A. C. Dhariwal, L. S. Chauhan, S. Venkatesh, Padmini Srikantiah. "Association of acute toxic encephalopathy with litchi consumption in an outbreak in Muzaffarpur, India, 2014: a case-control study." The Lancet Global Health. 2017, 5 (4), e458-e466; DOI: 10.1016/S2214-109X(17)30035-9; PMID: 28153514 https://www.ncbi.nlm.nih.gov/pubmed/28153514

10. Rebecca Coleman, Sharon W. Lemire, William Bragg, Alaine Garrett, Geovannie Ojeda-Torres, Rebekah Wharton, Elizabeth Hamelin, Jerry Thomas, Rudolph C. Johnson. "Development and validation of a high-throughput online solid-phase extraction–liquid chromatography–tandem mass spectrometry method for the detection of gonyautoxins 1&4 and gonyautoxins 2&3 in human urine." Biomedical Chromatography. 2017, 31 (9), e3954, 1-9; DOI: 10.1002/bmc.3954; PMID: 28186342 https://www.ncbi.nlm.nih.gov/pubmed/28186342

11. Rebekah E. Wharton, Melanie C. Feyereisen, Andrea L. Gonzalez, Nicole L. Abbott, Elizabeth I. Hamelin, Rudolph C. Johnson. "Quantification of saxitoxin in human blood by ELISA." Toxicon. 2017, 133, 110-115; DOI: 10.1016/j.toxicon.2017.05.009; PMID: 28495477 https://www.ncbi.nlm.nih.gov/pubmed/28495477

12. Akshay C. Dhariwal, Srinivas Venkatesh, Aakash Shrivastava, Amit Chakrabarti, Jerry D. Thomas, Melissa D. Carter, Rudolph Johnson, Kayla F. Laserson, Padmini Srikantiah. "Routine fruit washing to prevent acute toxic encephalopathy – Authors' reply." The Lancet Global Health. 2017, 5 (9), e864; DOI: 10.1016/S2214-109X(17)30271-1; PMID: 28807179 https://www.ncbi.nlm.nih.gov/pubmed/28807179

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Division of Laboratory Sciences develops methods for measuring selected toxins to help improve detection and diagnosis during a public health response to biological toxins. More information can be found at http://www.cdc.gov/nceh/dls/.

Agents Microorganisms and/or toxins studied: Select Agents (HHS), Select Toxins (HHS), NIAID Category A Pathogens

Outdoor studies: Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?

Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID)

2. Where is it located (provide both address and geographical location)?

1600 Clifton Road N.E., Atlanta, Georgia 30333

3. Floor area of laboratory areas by containment level:

BSL-2	423 m^2
BSL-3	1220 m^2
BSL-4	533 m^2
Total laboratory floor area	2176 m^2

4. The organizational structure of each facility.

(i) **Total number of personnel:** 211

(ii) Division of personnel:

Military	5
Civilian	206

(iii) Division of personnel by category:

Scientists	184

Engineers	0
Technicians	16
Administrative and support staff	11

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Animal Science, Biochemistry, Bioinformatics, Biology, Biological Science, Cell Biology. Chemistry, Clinical Immunology, Ecology, Entomology, Epidemiology, Genetics, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Public Health, Statistics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Contractor staff = 49

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Agency for International Development (USAID)
Department of Defense (DOD)
Department of Health and Human Services (HHS)
Department of Homeland Security (DHS)
Department of State (DOS)

(vii) What are the funding levels for the following program areas:

Research	$ 12,183,135
Development	$ 4,767,795
Test and evaluation	$ 11,741,048
Total	$28,691,978

(viii) Briefly describe the publication policy of the facility:

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies
CDC Policy on "Oversight and clearance of dual use research of concern" is available online at: http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

1. Abad N, Malik T, Ariyarajah A, Ongpin P, Hogben M, McDonald SLR, Marrinan J, Massaquoi T, Thorson A, Ervin E, Bernstein K, Ross C, Liu WJ, Kroeger K, Durski KN, Broutet N, Knust B, Deen GF. Development of risk reduction behavioral counseling for Ebola virus disease survivors enrolled in the Sierra Leone Ebola Virus Persistence Study, 2015-2016. PLoS Negl Trop Dis. 2017;11(9):e0005827. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5593175/

2. Albarino CG, Wiggleton Guerrero L, Jenks HM, Chakrabarti AK, Ksiazek TG, Rollin PE, Nichol ST. Insights into Reston virus spillovers and adaption from virus whole genome sequences. PloS one. 2017;12(5):e0178224. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444788/

3. Amarasinghe GK, Bao Y, Basler CF, Bavari S, Beer M, Bejerman N, Blasdell KR, Bochnowski A, Briese T, Bukreyev A, Calisher CH, Chandran K, Collins PL, Dietzgen RG, Dolnik O, Durrwald R, Dye JM, Easton AJ, Ebihara H, Fang Q, Formenty P, Fouchier RAM, Ghedin E, Harding RM, Hewson R, Higgins CM, Hong J, Horie M, James AP, Jiang D, Kobinger GP, Kondo H, Kurath G, Lamb RA, Lee B, Leroy EM, Li M, Maisner A, Muhlberger E, Netesov SV, Nowotny N, Patterson JL, Payne SL, Paweska JT, Pearson MN, Randall RE, Revill PA, Rima BK, Rota P, Rubbenstroth D, Schwemmle M, Smither SJ, Song Q, Stone DM, Takada A, Terregino C, Tesh RB, Tomonaga K, Tordo N, Towner JS, Vasilakis N, Volchkov VE, Wahl-Jensen V, Walker PJ, Wang B, Wang D, Wang F, Wang LF, Werren JH, Whitfield AE, Yan Z, Ye G, Kuhn JH. Taxonomy of the order Mononegavirales: update 2017. Arch Virol. 2017;162(8):2493-504. https://www.ncbi.nlm.nih.gov/pubmed/28389807

4. Amman BR, Schuh AJ, Towner JS. Ebola Virus Field Sample Collection. Methods Mol Biol. 2017;1628:373-93. https://www.ncbi.nlm.nih.gov/pubmed/28573636

5. Amman BR, Swanepoel R, Nichol ST, Towner JS. Ecology of Filoviruses. Curr Top Microbiol Immunol. 2017; 411:23-61. https://www.ncbi.nlm.nih.gov/pubmed/28710694

6. Bao Y, Amarasinghe GK, Basler CF, Bavari S, Bukreyev A, Chandran K, Dolnik O, Dye JM, Ebihara H, Formenty P, Hewson R, Kobinger GP, Leroy EM, Muhlberger E, Netesov SV, Patterson JL, Paweska JT, Smither SJ, Takada A, Towner JS, Volchkov VE, Wahl-Jensen V, Kuhn JH. Implementation of Objective PASC-Derived Taxon Demarcation Criteria for Official Classification of Filoviruses. Viruses. 2017;9(5). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5454419/

7. Bugrysheva JV, Sue D, Gee JE, Elrod MG, Hoffmaster AR, Randall LB, Chirakul S, Tuanyok A, Schweizer HP, Weigel LM. Antibiotic Resistance Markers in Strain Bp1651 of Burkholderia pseudomallei Identified by Genome Sequence Analysis. Antimicrob Agents Chemother. 2017 Jun; 61(6). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444168/

8. Bugrysheva JV, Sue D, Gee JE, Elrod MG, Hoffmaster AR, Randall LB, Chirakul S,Tuanyok A, Schweizer HP, Weigel LM. Antibiotic Resistance Markers in Burkholderia pseudomallei Strain Bp1651 Identified by Genome Sequence Analysis. Antimicrob Agents Chemother. 2017 May 24;61(6). pii: e00010-17. https://doi.org/10.1128/AAC.00010-17

9. Cash-Goldwasser S, Maze MJ, Rubach MP, Biggs HM, Stoddard RA, Sharples KJ, Halliday JEB, Cleaveland S, Shand MC, Mmbaga BT, Muiruri C, Saganda W, Lwezaula BF, Kazwala RR, Maro VP, Crump JA. Risk Factors for Human Brucellosis in Northern Tanzania. Am J Trop Med Hyg.. 2017. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29231152?dopt=Abstract

10. Christian KA, Iuliano AD, Uyeki TM, Mintz ED, Nichol ST, Rollin P, Staples JE, Arthur RR. What We Are Watching-Top Global Infectious Disease Threats, 2013-2016: An Update from CDC's Global Disease Detection Operations Center. Health secur. 2017;15(5):453-62. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5661857/

11. Crawford MA, Fisher DJ, Leung LM, Lomonaco S, Lascols C, Cannatelli A, Giani T, Rossolini GM, Doi Y, Goodlett DR, Allard MW, Sharma SK, Khan E, Ernst RK, Hughes MA. CXC Chemokines Exhibit Bactericidal Activity against Multidrug-Resistant Gram-Negative Pathogens. MBio. 2017 Nov 14;8(6). pii:e01549-17. https://doi.org/10.1128/mBio.01549-17

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

***Objectives*:**
Activities at this facility include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, vaccine evaluation, medical countermeasure evaluation, determining the natural history of infectious organisms and assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. More information can be found at: http://www.cdc.gov/oid/.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA, Overlap), Select Toxins (HHS), NIAID Category A pathogens

***Outdoor Studies*:** Outdoor studies of biological aerosols were NOT conducted at the facility or off-site by facility personnel.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?

CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins

2. Where is it located (include both address and geographical location)?
3156 Rampart Road, Fort Collins, Colorado 80521

3. Floor area of laboratory areas by containment level:

BSL-2	0 m^2
BSL-3	421 m^2
BSL-4	0 m^2
Total laboratory floor area	421 m^2

4. The organizational structure of each facility.

(i) **Total number of personnel**	42

(ii) **Division of personnel**:

Military	0
Civilian	42

(iii) **Division of personnel by category**:

Scientists	15
Engineers	0
Technicians	11
Administrative and support staff	16

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Bacteriology, Bioinformatics, Biological Science, Cell Biology, Ecology, Entomology, Environmental Science, Epidemiology, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Structural Biology, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 6

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health & Human Services
Department of Defense (DoD) - partially
Department of State (DoS)
Department of Homeland Security (DHS)

(vii) What are the funding levels for the following programme areas:

Research	$678,235
Development	$0
Test and evaluation	$36,995
Total	$715,230

(viii) Briefly describe the publication policy of the facility:
Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.

The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies.

CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

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2. Elias SP, Keenan P, Kenney JL, Morris SR, Covino KM, Robinson S, Foss KA, Rand PW, Lubelczyk C, Lacombe EH, Mutebi JP, Evers D, Smith RP Jr. Seasonal Patterns in Eastern Equine Encephalitis Virus Antibody in Songbirds in Southern Maine. Vector Borne Zoonotic Dis. 2017 May;17(5):325-330. doi: 10.1089/vbz.2016.2029. Epub 2017 Mar 13. https://www.ncbi.nlm.nih.gov/pubmed/28287934

3. Forrester JD, Apangu T, Griffith K, Acayo S, Yockey B, Kaggwa J, Kugeler KJ, Schriefer M, Sexton C, Ben Beard C, Candini G, Abaru J, Candia B, Okoth JF, Apio H, Nolex L, Ezama G, Okello R, Atiku L, Mpanga J, Mead PS. Patterns of Human Plague in Uganda, 2008-2016. Emerg Infect Dis. 2017 Sep;23(9):1517-1521. doi: 10.3201/eid2309.170789. https://www.ncbi.nlm.nih.gov/pubmed/28820134

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6. Melman SD, Ettestad PE, VinHatton ES, Ragsdale JM, Takacs N, Onischuk LM, Leonard PM, Master SS, Lucero VS, Kingry LC, Petersen JM. Human case of bubonic plague resulting from the bite of a wild Gunnison's prairie dog during translocation from a plague-endemic area. Zoonoses Public Health. 2017 Nov 6. doi: 10.1111/zph.12419. [Epub ahead of print]. https://www.ncbi.nlm.nih.gov/pubmed/29110441

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

***Objectives*:**

CDC's Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the Department of Health and Human Services (HHS) and HHS/U.S. Department of Agriculture overlap lists. Within CDC, DVBD has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance and detection of each agent and molecular and antigenic characterization. More information can be found at: http://www.cdc.gov/ncezid/dvbd/.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

***Outdoor Studies*:**

No outdoor studies of biological aerosols were conducted at the facility or off-site by facility personnel.

National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

2. Where is it located (include both address and geographical location)?
903 South 4th Street, Hamilton, Montana 59840

3. Floor area of laboratory areas by containment level:

BSL-2	1361 m^2
BSL-3	407 m^2
BSL-4	1145 m^2
Total laboratory floor area	2913 m^2

4. The organizational structure of each facility.

(i) **Total number of personnel** = 122

(ii) **Division of personnel**:
Military = 0
Civilian = 122

(iii) **Division of personnel by category**:
Scientists = 76
Engineers = 0
Technicians = 40
Administrative and support staff = 6

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Entomology, Genetics, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 7

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$24,040,692
Development	$0
Test and evaluation	$0
Total	$24,040,692

(viii) Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine’s PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

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71. Winkler CW, Myers LM, Woods TA, Carmody AB, Taylor KG, Peterson KE. Lymphocytes have a role in protection, but not in pathogenesis, during La Crosse Virus infection in mice. Journal of neuroinflammation. 2017;14(1):62. Epub 2017/03/28. doi: 10.1186/s12974-017-0836-3. PubMed PMID: 28340587; PubMed Central PMCID: PMCPMC5364665. https://jneuroinflammation.biomedcentral.com/articles/10.1186/s12974-017-0836-3

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74. Winkler CW, Woods TA, Robertson SJ, McNally KL, Carmody AB, Best SM, et al. Cutting Edge: CCR2 Is Not Required for Ly6C(hi) Monocyte Egress from the Bone Marrow but Is Necessary for Migration within the Brain in La Crosse Virus Encephalitis. Journal of immunology (Baltimore, Md : 1950). 2018;200(2):471-6. Epub 2017/12/17.

doi: 10.4049/jimmunol.1701230. PubMed PMID: 29246952; PubMed Central PMCID: PMCPMC5760479. http://www.jimmunol.org/content/200/2/471.long

75. Winkler CW, Woods TA, Rosenke R, Scott DP, Best SM, Peterson KE. Sexual and Vertical Transmission of Zika Virus in anti-interferon receptor-treated Rag1-deficient mice. Scientific reports. 2017;7(1):7176. Epub 2017/08/05. doi: 10.1038/s41598-017-07099-7. PubMed PMID: 28775298; PubMed Central PMCID: PMCPMC5543051. https://www.nature.com/articles/s41598-017-07099-7

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Rocky Mountain Laboratories hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program. More information is available at http://www.niaid.nih.gov/about/organization/dir/rml/Pages/default.aspx.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap, USDA), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Fort Detrick (IRF-Frederick)

2. Where is it located (include both address and geographical location)?
8200 Research Plaza, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level:

BSL-2	878 m^2
BSL-3	0 m^2
BSL-4	1305 m^2
Total laboratory floor area	2183 m^2

4. The organizational structure of each facility.

(i) **Total number of personnel**	95

(ii) **Division of personnel**:

Military	0
Civilian	95

(iii) **Division of personnel by category**:

Scientists	32
Engineers	2

Technicians	58
Administrative and support staff	3

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Aerosol Science, Analytical Biochemistry, Biochemistry, Biological Science, Cell Biology, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 87

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$23,608,348
Development	$0
Test and evaluation	$0
Total	$23,608,348

(viii) Briefly describe the publication policy of the facility:
All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Bennett RS, Huzella LM, Jahrling PB, Bollinger L, Olinger GG, Jr., Hensley LE. Nonhuman Primate Models of Ebola Virus Disease. Current topics in microbiology and immunology. 2017;411:171-93. Epub 2017/06/24. doi: 10.1007/82_2017_20. PubMed PMID: 28643203. https://link.springer.com/chapter/10.1007%2F82_2017_20

2. Cong Y, Lentz MR, Lara A, Alexander I, Bartos C, Bohannon JK, et al. Loss in lung volume and changes in the immune response demonstrate disease progression in African green monkeys infected by small-particle aerosol and intratracheal exposure to Nipah virus. PLoS neglected tropical diseases. 2017;11(4):e0005532. Epub 2017/04/08. doi: 10.1371/journal.pntd.0005532. PubMed PMID: 28388650; PubMed Central PMCID: PMCPMC5397074. http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005532

3. Cornish JP, Diaz L, Ricklefs SM, Kanakabandi K, Sword J, Jahrling PB, et al. Sequence of Reston Virus Isolate AZ-1435, an Ebolavirus Isolate Obtained during the 1989-1990 Reston Virus Epizootic in the United States. Genome announcements. 2017;5(2). Epub 2017/01/14. doi: 10.1128/genomeA.01448-16. PubMed PMID: 28082493; PubMed Central PMCID: PMCPMC5256212. http://genomea.asm.org/content/5/2/e01448-16

4. Dyall J, Gross R, Kindrachuk J, Johnson RF, Olinger GG, Jr., Hensley LE, et al. Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome: Current Therapeutic Options and Potential Targets for Novel Therapies. Drugs. 2017;77(18):1935-66. Epub 2017/11/17. doi: 10.1007/s40265-017-0830-1. PubMed PMID: 29143192; PubMed Central PMCID: PMCPMC5733787. https://link.springer.com/article/10.1007%2Fs40265-017-0830-1

5. Dyall J, Hart BJ, Postnikova E, Cong Y, Zhou H, Gerhardt DM, et al. Interferon-beta and Interferon-gamma Are Weak Inhibitors of Ebola Virus in Cell-Based Assays. The Journal of infectious diseases. 2017;215(9):1416-20. Epub 2017/04/04. doi: 10.1093/infdis/jix134. PubMed PMID: 28368541. https://academic.oup.com/jid/article/215/9/1416/3077275

6. Dyall J, Johnson RF, Chefer S, Leyson C, Thomasson D, Seidel J, et al. [(18)F]-Fluorodeoxyglucose Uptake in Lymphoid Tissue Serves as a Predictor of Disease Outcome in the Nonhuman Primate Model of Monkeypox Virus Infection. Journal of virology. 2017;91(21). Epub 2017/08/18. doi: 10.1128/jvi.00897-17. PubMed PMID: 28814515; PubMed Central PMCID: PMCPMC5640857. http://jvi.asm.org/content/91/21/e00897-17.long

7. Honko AN, Johnson JC, Marchand JS, Huzella L, Adams RD, Oberlander N, et al. High dose sertraline monotherapy fails to protect rhesus macaques from lethal challenge with Ebola virus Makona. Scientific reports. 2017;7(1):5886. Epub 2017/07/21. doi: 10.1038/s41598-017-06179-y. PubMed PMID: 28725019; PubMed Central PMCID: PMCPMC5517626. https://www.nature.com/articles/s41598-017-06179-y

8. Moncla LH, Weiler AM, Barry G, Weinfurter JT, Dinis JM, Charlier O, et al. Within-Host Evolution of Simian Arteriviruses in Crab-Eating Macaques. Journal of virology. 2017;91(4). Epub 2016/12/16. doi: 10.1128/jvi.02231-16. PubMed PMID: 27974564; PubMed Central PMCID: PMCPMC5286893. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5286893/

9. Nelson EA, Dyall J, Hoenen T, Barnes AB, Zhou H, Liang JY, et al. The phosphatidylinositol-3-phosphate 5-kinase inhibitor apilimod blocks filoviral entry and infection. PLoS neglected tropical diseases. 2017;11(4):e0005540. Epub 2017/04/14. doi: 10.1371/journal.pntd.0005540. PubMed PMID: 28403145; PubMed Central PMCID: PMCPMC5402990. http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005540

10. Walpita P, Cong Y, Jahrling PB, Rojas O, Postnikova E, Yu S, et al. A VLP-based vaccine provides complete protection against Nipah virus challenge following multiple-dose or single-dose vaccination schedules in a hamster model. NPJ vaccines. 2017;2:21. Epub 2017/12/22. doi: 10.1038/s41541-017-0023-7. PubMed PMID: 29263876; PubMed Central PMCID: PMCPMC5627259. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5627259/

11. Wirblich C, Coleman CM, Kurup D, Abraham TS, Bernbaum JG, Jahrling PB, et al. One-Health: a Safe, Efficient, Dual-Use Vaccine for Humans and Animals against Middle East Respiratory Syndrome Coronavirus and Rabies Virus. Journal of virology. 2017;91(2). Epub 2016/11/04. doi: 10.1128/jvi.02040-16. PubMed PMID: 27807241; PubMed Central PMCID: PMCPMC5215356. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5215356/

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Fort Detrick in Frederick, Maryland manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Battelle Memorial Institute facilitates research performed at the IRF-Frederick with direction from the IRF Scientific Steering Committee.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

2. Where is it located (include both address and geographical location)?
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:

BSL-2	2725 m^2
BSL-3	1356 m^2
BSL-4	0 m^2
Total laboratory floor area	4081 m^2

4. The organizational structure of each facility.
(i) **Total number of personnel:** 138

(ii) **Division of personnel**:

Military	0
Civilian	138

(iii) **Division of personnel by category**:

Scientists	102
Engineers	0
Technicians	29
Administrative and support staff	7

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Bacteriology, Biological Science, Chemistry, Immunology, Medicine, Microbiology, Molecular Biology, Parasitology, Pathogenesis, Toxicology, Vaccine Evaluation, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 22

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	\$32,852,059
Development	\$0
Test and evaluation	\$0
Total	\$32,852,059

(viii) Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Ake JA, Schuetz A, Pegu P, Wieczorek L, Eller MA, Kibuuka H, et al. Safety and Immunogenicity of PENNVAX-G DNA Prime Administered by Biojector 2000 or CELLECTRA Electroporation Device With Modified Vaccinia Ankara-CMDR Boost. The Journal of infectious diseases. 2017;216(9):1080-90. Epub 2017/10/03. doi: 10.1093/infdis/jix456. PubMed PMID: 28968759. https://academic.oup.com/jid/article/216/9/1080/4102981

2. Americo JL, Earl PL, Moss B. Droplet digital PCR for rapid enumeration of viral genomes and particles from cells and animals infected with orthopoxviruses. Virology. 2017;511:19-22. Epub 2017/08/13. doi: 10.1016/j.virol.2017.08.005. PubMed PMID: 28802157; PubMed Central PMCID: PMCPMC5623639. http://www.sciencedirect.com/science/article/pii/S0042682217302593?via%3Dihub

3. Angeletti D, Frank GM, Yewdell JW. Flow-Cytometric Method Measuring B Cell Surface Immunoglobulin Avidity. Methods in molecular biology (Clifton, NJ). 2017;1623:181-9. Epub 2017/06/08. doi: 10.1007/978-1-4939-7095-7_15. PubMed PMID: 28589357. https://link.springer.com/protocol/10.1007%2F978-1-4939-7095-7_15

4. Angeletti D, Gibbs JS, Angel M, Kosik I, Hickman HD, Frank GM, et al. Defining B cell immunodominance to viruses. Nature immunology. 2017;18(4):456-63. Epub 2017/02/14. doi: 10.1038/ni.3680. PubMed PMID: 28192417; PubMed Central PMCID: PMCPMC5360521. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360521/

5. Angeletti D, Yewdell JW. Is It Possible to Develop a "Universal" Influenza Virus Vaccine? Outflanking Antibody Immunodominance on the Road to Universal Influenza Vaccination. Cold Spring Harbor perspectives in biology. 2017. Epub 2017/07/01. doi: 10.1101/cshperspect.a028852. PubMed PMID: 28663210. http://cshperspectives.cshlp.org/content/early/2017/06/29/cshperspect.a028852.long

6. Angelo MA, Grifoni A, O'Rourke PH, Sidney J, Paul S, Peters B, et al. Human CD4(+) T Cell Responses to an Attenuated Tetravalent Dengue Vaccine Parallel Those Induced by Natural Infection in Magnitude, HLA Restriction, and Antigen Specificity. Journal of virology. 2017;91(5). Epub 2016/12/16. doi: 10.1128/jvi.02147-16. PubMed PMID: 27974563; PubMed Central PMCID: PMCPMC5309943. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5309943/

7. Arbuckle JH, Gardina PJ, Gordon DN, Hickman HD, Yewdell JW, Pierson TC, et al. Inhibitors of the Histone Methyltransferases EZH2/1 Induce a Potent Antiviral State and

Suppress Infection by Diverse Viral Pathogens. mBio. 2017;8(4). Epub 2017/08/16. doi: 10.1128/mBio.01141-17. PubMed PMID: 28811345; PubMed Central PMCID: PMCPMC5559635. http://mbio.asm.org/content/8/4/e01141-17.long

8. Arora K, Ochoa-Montano B, Tsang PS, Blundell TL, Dawes SS, Mizrahi V, et al. Correction for Arora et al., "Respiratory Flexibility in Response to Inhibition of Cytochrome c Oxidase in Mycobacterium tuberculosis". Antimicrobial agents and chemotherapy. 2017;61(9). Epub 2017/08/26. doi: 10.1128/aac.01429-17. PubMed PMID: 28839085; PubMed Central PMCID: PMCPMC5571366. http://aac.asm.org/content/61/9/e01429-17.long

9. Barber DL. The Helper T Cell's Dilemma in Tuberculosis. Cell host & microbe. 2017;21(6):655-6. Epub 2017/06/16. doi: 10.1016/j.chom.2017.06.004. PubMed PMID: 28618262. http://www.sciencedirect.com/science/article/pii/S193131281730210X?via%3Dihub

10. Bardina SV, Brown JA, Michlmayr D, Hoffman KW, Sum J, Pletnev AG, et al. Chemokine Receptor Ccr7 Restricts Fatal West Nile Virus Encephalitis. Journal of virology. 2017;91(10). Epub 2017/03/31. doi: 10.1128/jvi.02409-16. PubMed PMID: 28356527; PubMed Central PMCID: PMCPMC5411599. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5411599/

11. Boonnak K, Matsuoka Y, Wang W, Suguitan AL, Jr., Chen Z, Paskel M, et al. Development of Clade-Specific and Broadly Reactive Live Attenuated Influenza Virus Vaccines against Rapidly Evolving H5 Subtype Viruses. Journal of virology. 2017;91(15). Epub 2017/05/12. doi: 10.1128/jvi.00547-17. PubMed PMID: 28490598; PubMed Central PMCID: PMCPMC5512263. http://jvi.asm.org/content/91/15/e00547-17.long

12. Cotter CA, Earl PL, Wyatt LS, Moss B. Preparation of Cell Cultures and Vaccinia Virus Stocks. Current protocols in protein science. 2017;89:5.12.1-5..8. Epub 2017/08/02. doi: 10.1002/cpps.34. PubMed PMID: 28762495. http://onlinelibrary.wiley.com/doi/10.1002/cpps.34/abstract;jsessionid=F657D6BF5FEAD63884F290C47BC9BC32.f03t03

13. Czako R, Vogel L, Lamirande EW, Bock KW, Moore IN, Ellebedy AH, et al. In Vivo Imaging of Influenza Virus Infection in Immunized Mice. mBio. 2017;8(3). Epub 2017/06/01. doi: 10.1128/mBio.00714-17. PubMed PMID: 28559489; PubMed Central PMCID: PMCPMC5449660. http://mbio.asm.org/content/8/3/e00714-17.long

14. Da F, Joo HS, Cheung GYC, Villaruz AE, Rohde H, Luo X, et al. Phenol-Soluble Modulin Toxins of Staphylococcus haemolyticus. Frontiers in cellular and infection microbiology. 2017;7:206. Epub 2017/06/10. doi: 10.3389/fcimb.2017.00206. PubMed PMID: 28596942; PubMed Central PMCID: PMCPMC5442197. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442197/

15. Dickey SW, Cheung GYC, Otto M. Different drugs for bad bugs: antivirulence strategies in the age of antibiotic resistance. Nature reviews Drug discovery. 2017;16(7):457-71. Epub 2017/03/25. doi: 10.1038/nrd.2017.23. PubMed PMID: 28337021. https://www.nature.com/articles/nrd.2017.23

16. Dickey SW, Otto M. Lipoyl-E2-PDH Gets a Second Job. Cell host & microbe. 2017;22(5):581-3. Epub 2017/11/10. doi: 10.1016/j.chom.2017.10.018. PubMed PMID: 29120739. http://www.sciencedirect.com/science/article/pii/S1931312817304535?via%3Dihub

17. Earl PL, Americo JL, Moss B. Insufficient Innate Immunity Contributes to the Susceptibility of the Castaneous Mouse to Orthopoxvirus Infection. Journal of virology. 2017;91(19). Epub 2017/07/28. doi: 10.1128/jvi.01042-17. PubMed PMID: 28747505; PubMed Central PMCID: PMCPMC5599762. http://jvi.asm.org/content/91/19/e01042-17.long

18. Ebner P, Luqman A, Reichert S, Hauf K, Popella P, Forchhammer K, et al. Non-classical Protein Excretion Is Boosted by PSMalpha-Induced Cell Leakage. Cell reports. 2017;20(6):1278-86. Epub 2017/08/10. doi: 10.1016/j.celrep.2017.07.045. PubMed PMID: 28793253. http://www.sciencedirect.com/science/article/pii/S2211124717310240?via%3Dihub

19. Gangadhara S, Kwon YM, Jeeva S, Quan FS, Wang B, Moss B, et al. Vaccination with Combination DNA and Virus-Like Particles Enhances Humoral and Cellular Immune Responses upon Boost with Recombinant Modified Vaccinia Virus Ankara Expressing Human Immunodeficiency Virus Envelope Proteins. Vaccines. 2017;5(4). Epub 2017/12/20. doi: 10.3390/vaccines5040052. PubMed PMID: 29257056; PubMed Central PMCID: PMCPMC5748618. http://www.mdpi.com/2076-393X/5/4/52

20. Gaudinski MR, Houser KV, Morabito KM, Hu Z, Yamshchikov G, Rothwell RS, et al. Safety, tolerability, and immunogenicity of two Zika virus DNA vaccine candidates in healthy adults: randomised, open-label, phase 1 clinical trials. Lancet (London, England). 2017. Epub 2017/12/09. doi: 10.1016/s0140-6736(17)33105-7. PubMed PMID: 29217376. http://www.sciencedirect.com/science/article/pii/S0140673617331057?via%3Dihub

21. Goo L, VanBlargan LA, Dowd KA, Diamond MS, Pierson TC. A single mutation in the envelope protein modulates flavivirus antigenicity, stability, and pathogenesis. PLoS pathogens. 2017;13(2):e1006178. Epub 2017/02/17. doi: 10.1371/journal.ppat.1006178. PubMed PMID: 28207910; PubMed Central PMCID: PMCPMC5312798. http://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1006178

22. Grabowski JM, Tsetsarkin KA, Long D, Scott DP, Rosenke R, Schwan TG, et al. Flavivirus Infection of Ixodes scapularis (Black-Legged Tick) Ex Vivo Organotypic Cultures and Applications for Disease Control. mBio. 2017;8(4). Epub 2017/08/24. doi: 10.1128/mBio.01255-17. PubMed PMID: 28830948; PubMed Central PMCID: PMCPMC5565970. http://mbio.asm.org/content/8/4/e01255-17.long

23. Grifoni A, Angelo M, Sidney J, Paul S, Peters B, de Silva AD, et al. Patterns of Cellular Immunity Associated with Experimental Infection with rDEN2Delta30 (Tonga/74) Support Its Suitability as a Human Dengue Virus Challenge Strain. Journal of virology. 2017;91(8). Epub 2017/02/06. doi: 10.1128/jvi.02133-16. PubMed PMID: 28148797; PubMed Central

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100. Yewdell JW, Rimmelzwaan GF. Editorial overview: Viral immunology: Dealing with bad news. Current opinion in virology. 2017;22:viii-x. Epub 2017/03/11. doi: 10.1016/j.coviro.2017.02.002. PubMed PMID: 28279326.

http://www.sciencedirect.com/science/article/pii/S187962571730010X?via%3Dihub

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102. Zhao J, Alshukairi AN, Baharoon SA, Ahmed WA, Bokhari AA, Nehdi AM, et al. Recovery from the Middle East respiratory syndrome is associated with antibody and T-cell responses. Science immunology. 2017;2(14). Epub 2017/08/06. doi: 10.1126/sciimmunol.aan5393. PubMed PMID: 28778905; PubMed Central PMCID: PMCPMC5576145. http://immunology.sciencemag.org/content/2/14/eaan5393.long

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: At the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, the Laboratory of Infectious Diseases (LID) focuses on vaccine development, host immune response to viruses, and viral molecular biology and genetics. The Laboratory of Parasitic Diseases (LPD) conducts basic and applied research on the prevention, control, and treatment of a variety of parasitic and bacterial diseases of global importance. The Laboratory of Viral Diseases (LVD) carries out investigations on the molecular biology of viruses, the interactions of viruses with host cells, the pathogens of viral diseases, and host defense mechanisms. The Laboratory of Clinical Infectious Diseases (LCID) conducts clinical and basic studies of important human infections and immunological diseases. The Laboratory of Bacteriology (LB) studies bacteria that cause important human infections to identify novel or improved strategies to control bacterial diseases, including development of diagnostics, vaccines, and therapeutics. More information can be found at http://www.nih.gov/news-events/news-releases/nih-dedicates-cw-bill-young-center-biodefense-emerging-infectious-diseases.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA), NIAID Category A pathogen

Outdoor studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes

1. What is the name of the facility?
Dale and Betty Bumpers Vaccine Research Center (VRC)

2. Where is it located (include both address and geographical location)?
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:

BSL-2	104m^2
BSL-3	0m^2
BSL-4	0m^2
Total laboratory floor area	104 m^2

4. The organizational structure of each facility.
(i) **Total number of personnel:** 12

(ii) **Division of personnel**:

Military:	0
Civilian:	12

(iii) **Division of personnel by category**:

Scientists:	12
Engineers:	0
Technicians:	0
Administrative and support staff:	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Biological Science

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 2

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$1,114,169
Development	0
Test and evaluation	0
Total	$1,114,169

(viii) Briefly describe the publication policy of the facility:
All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the

published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Graham BS, Sullivan NJ. Emerging viral diseases from a vaccinology perspective: preparing for the next pandemic. Nature immunology. 2018;19(1):20-8. Epub 2017/12/05. doi: 10.1038/s41590-017-0007-9. PubMed PMID: 29199281. https://www.nature.com/articles/s41590-017-0007-9

2. Ledgerwood JE, DeZure AD, Stanley DA, Coates EE, Novik L, Enama ME, et al. Chimpanzee Adenovirus Vector Ebola Vaccine. The New England journal of medicine. 2017;376(10):928-38. Epub 2014/11/27. doi: 10.1056/NEJMoa1410863. PubMed PMID: 25426834. http://www.nejm.org/doi/full/10.1056/NEJMoa1410863

3. Liang F, Lindgren G, Sandgren KJ, Thompson EA, Francica JR, Seubert A, et al. Vaccine priming is restricted to draining lymph nodes and controlled by adjuvant-mediated antigen uptake. Science translational medicine. 2017;9(393). Epub 2017/06/09. doi: 10.1126/scitranslmed.aal2094. PubMed PMID: 28592561. http://stm.sciencemag.org/content/9/393/eaal2094.short

4. Regules JA, Beigel JH, Paolino KM, Voell J, Castellano AR, Hu Z, et al. A Recombinant Vesicular Stomatitis Virus Ebola Vaccine. The New England journal of medicine. 2017;376(4):330-41. Epub 2015/04/02. doi: 10.1056/NEJMoa1414216. PubMed PMID: 25830322; PubMed Central PMCID: PMCPMC5408576. http://www.nejm.org/doi/full/10.1056/NEJMoa1414216

5. Zou Z, Misasi J, Sullivan N, Sun PD. Overexpression of Ebola virus envelope GP1 protein. Protein expression and purification. 2017;135:45-53. Epub 2017/05/02. doi: 10.1016/j.pep.2017.04.010. PubMed PMID: 28458053; PubMed Central PMCID: PMCPMC5549271. http://www.sciencedirect.com/science/article/pii/S1046592816302078?via%3Dihub

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The mission of the Vaccine Research Center (VRC) is to conduct research that facilitates the development of effective vaccines for human disease. The research focus of the Biodefense Research Section comprises three areas: development of vaccines and antivirals against hemorrhagic fever viruses such as Ebola, Marburg, and Lassa; studies of the mechanism of vaccine-induced immune protection and host immunity to natural infection; basic research to understand the mechanism of virus replication (entry) and neutralization.

Microorganisms and/or toxins studied: No U.S. Select Agents, NIAID Category A pathogens, or applicable simulants were used.

Outdoor studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Foreign Disease-Weed Science Research Unit

2. Where is it located (provide both address and geographical location)?
1301 Ditto Avenue, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	105 m^2
BSL-3:	950 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,055 m^2

4. The organizational structure of each facility:

(i) **Total number of personnel:** 34

(ii) **Division of personnel:**

Military	0
Civilian	34

(iii) **Division of personnel by category:**

Scientists	9
Engineers	0
Technicians	15
Administrative and support staff	10

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**
Agronomy, Biological Science, Genomics, Horticulture, Bacteriology, Microbial Forensics, Molecular Diagnostics, Plant Biochemistry, Plant Molecular Biology, Plant Pathology, Plant Physiology, Proteomics, Virology, Weed Science

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Agriculture (USDA)

(vii) **What are the funding levels for the following program areas:**

Research	$4,000,000
Development	$0
Test and evaluation	$0
Total	$4,000,000

(viii) **Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=80-44-05-00.)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Sechler, A.J., Tancos, M.A., Schneider, D.J., et al. Whole genome sequence of two Rathayibacter toxicus strains reveals a tunicamycin biosynthetic cluster similar to Streptomyces chartreusis. PLoS One. 2017; Volume 12, Issue 8, e0183005. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183005

2. Schneider, W.L., Sechler, A.J., Rogers, E.E. Complete genome sequence of the Rathayibacter toxicus phage NCPPB3778. Genome Announc. 2017; 5(42):e00671-17. https://doi.org/10.1128/genomeA.00671-17 . http://genomea.asm.org/content/5/42/e00671-17.short

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

***Objectives*:** The Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's unique BL-3 plant pathogen laboratory and greenhouse containment facilities. 1) The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm. 2) The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00.

***Microorganisms and/or Toxins Studied*:**
Select Agents (Plant Protection and Quarantine, PPQ).

***Outdoor Studies*:** No research work is done outdoors with infectious organisms.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

National Animal Disease Center (NADC)

2. Where is it located (provide both address and geographical location)?

1920 Dayton Avenue, Ames, Iowa 50010

3. Floor area of laboratory areas by containment level (m^2):

BSL-2: 4,410 m^2
BSL-3: 2,489 m^2
BSL-4: 0 m^2
Total laboratory floor area: 6,899 m^2

In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level that can accommodate food producing animals and various wildlife species). Biocontainment enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in/out of each animal room; heat-treated waste; steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors; and epoxy-covered surfaces. NADC also has two large biocontainment buildings that are considered ABSL-2-enhanced.

ABSL-2: 3,467.7 m^2
ABSL-3: 160.5 m^2
ABSL-3Ag: 1,581.6 m^2
Total biocontainment facility floor area: 5209.8 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 10

(ii) Division of personnel:

Military	0
Civilian	10

(iii) Division of personnel by category:

Scientists	8
Engineers	0
Technicians	2
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:

Agricultural Engineering, Animal Science, Biochemistry, Bioinformatics, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Ecology, Genetics, Genomics, Immunology, Infectious Disease, Mass Spectrometry, Microbiology, Molecular Biology, Pathogenesis, Pathology, Physiology, Prionology, Proteomics, Statistics, Structural Biology, Vaccine Evaluation, Veterinarian, Veterinary Clinical Research, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number:

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Agriculture (USDA)
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following program areas:

Research	$6,200,000
Development	$0
Test and evaluation	$0
Total	$6,200,000

(viii) Briefly describe the publication policy of the facility:

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=50-30-20-00.)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Abente, E.J., Kitikoon, P., Lager, K.M., et al. A highly pathogenic avian-derived influenza virus H5N1 with 2009 pandemic H1N1 internal genes demonstrates increased replication and transmission in pigs. J Gen Virol. 2017; 98(1):18-30. https://www.ncbi.nlm.nih.gov/pubmed/28206909

2. Olsen, S.C., Wilson-Welder, J.H., Nol, P., Rhyan, J., Srirangathan, N. Immunogenicity and efficacy of a rough Brucella suis vaccine delivered orally or parenterally to feral swine. Int J Vaccine Res. 2017; 2(1): 6. https://www.ars.usda.gov/research/publications/publication/?seqNo115=304318

3. Pederson, K., Bauer, N., Gidlewski, T., et al. Identification of Brucella spp. in feral swine (Sus scrofa) at abattoirs in Texas, USA. Zoonoses Public Health. 2017; doi: 10.1111/zph.12359. https://www.ncbi.nlm.nih.gov/pubmed/28391650

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Support the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis. Specifically, the research programs aim to produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases.

***Microorganisms and/or Toxins Studied*:**
Select Agents (Overlap, USDA).

***Outdoor Studies*:** No research work is done outdoors with infectious organisms.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Southeast Poultry Research Laboratory

2. Where is it located (provide both address and geographical location)?
934 College Station Road, Athens, Georgia 30605

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,138 m^2
BSL-3:	624 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,762 m^2

4. The organizational structure of each facility:

(i)	**Total number of personnel:**	35
(ii)	**Division of personnel:**	
	Military	0
	Civilian	35
(iii)	**Division of personnel by category:**	
	Scientists	7
	Engineers	0
	Technicians	23
	Administrative and support staff	5

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Animal Science, Bioinformatics, Biological Science, Biotechnology, Cell Biology, Computational Biology, Epidemiology, Genetics, Genomics, Immunology, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number:
No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Agriculture (USDA)
Department of Health and Human Services (HHS)
Department of Defense (DoD) – partly
Non-Profit Associations
Private Sector Companies
Department of State

(vii) What are the funding levels for the following program areas:

Research	$4,600,000
Development	$0
Test and evaluation	$0
Total	$4,600,000

(viii) Briefly describe the publication policy of the facility:

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=60-40-10-30.)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Chrzastek, K., Lee, D., Smith, D.M., et al. Use of Sequence-Independent, Single-Primer-Amplification (SISPA) for rapid detection, identification, and characterization of avian RNA viruses. Virol. 2017; 509:159-166. doi:10.1016/j.virol.2017.06.019. https://www.ncbi.nlm.nih.gov/pubmed/28646651

2. Dimitrov, K.M., Afonso, C.L., Yu, Q., Miller, P.J. Newcastle disease vaccines- a solved problem or a continuous challenge? Vet Microbiol. 2017; 206:126-136. doi:10.1016/j.vetmic.2016.12.019. https://www.ncbi.nlm.nih.gov/pubmed/28024856

3. Dimitrov, K.M., Sharma, P., Volkening, J.D., et al. A robust and cost-effective approach to sequence and analyze complete genomes of small RNA viruses. Virol J. 2017; 14(2017):72. doi: 10.1186/s12985-017-0741-5. https://www.ars.usda.gov/research/publications/publication/?seqNo115=338280

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5. Kapczynski, D.R., Sylte, M.J., Killian, M.L., et al. Protection of commercial turkeys following inactivated or recombinant H5 vaccine application against the 2015 U.S. H5N2 clade 2.3.4.4 highly pathogenic avian influenza virus. Vet Immunol Immunopathol. 2017; 191(2017):74-79. doi:10.1016/j.vetimm.2017.08.001. https://www.ncbi.nlm.nih.gov/pubmed/28895870
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives**:** Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies; prediction of disease outbreaks; molecular epidemiology; and understanding of disease pathogenesis. Produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and improve our understanding of the genetic and pathobiological basis of virulence. This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has one research unit that conducts biological defense work: Exotic and Emerging Avian Viral Diseases Research Unit. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/main/site_main.htm?modecode=60-40-10-00.

***Microorganisms and/or Toxins Studied*:**
Select Agents (USDA)

***Outdoor Studies*:** No research work is done outdoors with infectious organisms.

Form B

BWC - Confidence Building Measure

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

United States of America

April 15, 2018

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Human Disease Events

Seoul Virus Outbreak Associated with Pet Rats:

In December 2016 - January 2017, the United States Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services (HHS) assisted health officials in 15 states to investigate an outbreak of Seoul virus that infected 11 people in Illinois, Wisconsin, and Colorado. The original indicators were reports of illnesses in December 2016 in two individuals who operated a home-based rat-breeding facility (rattery) in Wisconsin. CDC confirmed the infections using serology and molecular techniques in pet rats from ratteries in Wisconsin, Illinois, and Minnesota. Following depopulation of those ratteries, investigations continued in places to where rats from those locations were distributed before the detection of the outbreak. A trace-out investigation was conducted to identify additional human and rat infections and prevent further transmission of SEOV. Ultimately, 31 facilities in 11 states identified human or rat SEOV infections (specimens from more than 1500 rodents were received and tested by the VSPB laboratory group). Serology from 163 humans found 17 (10.4%) with recent acute infection; of these, 3 (17.6%) were hospitalized and no deaths occurred.

Follow-up investigations by CDC and Canadian provincial officials indicated that there had been potentially infectious rats exchanged between the United States and Canada. Canada subsequently identified three cases among people who had contact with pet rats with links to the same U.S. locations. The investigations confirmed that the affected breeding facilities were limited to the supply and trade of pet rats. None of those small facilities supplied rats to research facilities or to breeding facilities supplying research facilities.

Seoul virus is a type of Hantavirus transmitted from rodents to people after exposure to aerosolized urine, droppings, or saliva of infected rodents or after exposure to dust from their nests or bedding. Transmission may also occur from rat bites or when contaminated materials are directly introduced into broken skin or onto mucous membranes. The incubation period is 1 to 8 weeks; however, most individuals develop symptoms within 1 to 2 weeks after exposure. Seoul virus infection symptoms can range from mild to severe. Initial symptoms begin suddenly and include fever, intense headaches, back and abdominal pain, chills, nausea, and blurred vision. Individuals may have flushing of the face, inflammation or redness of the eyes, or a rash. Later symptoms can include low blood pressure, acute shock, and acute kidney failure. Asymptomatic infections can also occur. Seoul virus infection is not transmissible human-to-human.

For more information, see: https://www.cdc.gov/mmwr/volumes/67/wr/mm6704a5.htm.

Human Infection with Influenza A (H3N2) Variant Virus:

On February 23, 2017, a child in Texas under 5 years of age with no underlying medical conditions developed an upper respiratory illness. On February 24, the patient was seen at an emergency department located on a U.S. military base. A respiratory specimen was collected for rapid influenza testing, which was positive for influenza A virus. As part of the U.S. Department of Defense (DoD) Global, Laboratory-Based Influenza Surveillance Program, the specimen was forwarded to the U.S. Air Force School of Aerospace Medicine (USAFSAM), Epidemiology Laboratory Service at the Wright-Patterson Air Force Base in Ohio. Real-time reverse transcription polymerase chain reaction (RT-PCR) testing conducted at the USAFSAM laboratory on April 26 was presumptively positive for an influenza A(H3N2) variant virus A(H3N2v). The specimen was forwarded to CDC on April 27; subsequent testing confirmed influenza A(H3N2)v by RT-PCR and genetic sequence analysis. This was the first influenza A(H3N2)v infection identified in the United States in 2017 and was reported to WHO per U.S. policy regarding recurrent yet variant (non-seasonal) influenza viruses. The patient was not hospitalized and has completely recovered from their illness. Swine contact at an agricultural event was reported in the week preceding illness onset.

Since reporting of novel influenza A viruses became nationally notifiable in 2005, 434 human infections with A(H3N2)v, including this one, have been reported to CDC.

For more information, see: https://www.cdc.gov/flu/weekly/weeklyarchives2016-2017/Week17.htm.

Human Infection with Influenza A (H1N2) Variant Virus:

During the week of July 22, 2017, a child under 18 years of age in Ohio with no underlying medical conditions developed an influenza-like illness. The child was seen by their health care provider. A respiratory specimen was collected for influenza testing and was forwarded to the Ohio Department of Health (ODH) Laboratory as part of routine surveillance activities. Real-time reverse transcription polymerase chain reaction (RT-PCR) testing suggested the specimen to be an influenza A(H1) variant virus. The ODH laboratory forwarded the specimen to the U.S. Centers for Disease Control and Prevention (CDC) for additional testing. On July 31, CDC confirmed an influenza A(H1N2) variant A(H1N2)v virus using RT-PCR and partial genome sequence analysis. This was the first influenza A H1N2v virus infection identified in the United States in 2017 and was reported to WHO per U.S. policy regarding recurrent yet variant (non-seasonal) influenza viruses. The child was not hospitalized and has completely recovered. Swine contact at an agricultural event was reported in the week preceding illness onset. No human-to-human transmission has been identified, and none of the child's close contacts reported any respiratory illness.

Since reporting of novel influenza A viruses became nationally notifiable in 2005, 13 human infections with A(H1N2)v, including this one, have been reported to CDC.

For more information, see: https://www.cdc.gov/flu/weekly/weeklyarchives2016-2017/Week30.htm.

Human Infection with Influenza A(H1N1) Variant Virus:

On October 21, 2017, an adult under 50 years of age in Iowa with no underlying medical conditions developed an influenza-like illness. The person was seen at an emergency department, and a respiratory specimen was collected for influenza testing. A rapid influenza diagnostic test used at the hospital laboratory indicated an influenza A virus infection. The specimen was forwarded to the State Hygienic Laboratory at the University of Iowa as part of routine influenza surveillance activities. Real-time reverse transcription polymerase chain reaction (RT-PCR) testing conducted at the public health laboratory indicated a seasonal influenza A(H1N1)pdm09 virus. The specimen was then forwarded to the National Influenza Reference Center in Wisconsin per national surveillance specimen submission guidelines. Genetic sequencing results were suggestive of an influenza A(H1N1) variant A(H1N1)v virus. The specimen was forwarded to the U.S. Centers for Disease Control and Prevention (CDC) for additional testing. On November 20, CDC confirmed an A(H1N1)v virus using RT-PCR and genome sequence analysis. This is the first influenza A(H1N1)v virus infection identified in the United States in 2017 and was reported to WHO per U.S. policy regarding recurrent yet variant (non-seasonal) influenza viruses. The patient was not hospitalized and has completely recovered. Direct exposure to swine at a swine premises in the week preceding illness onset was reported. No human-to-human transmission has been identified. Since reporting of novel influenza A viruses became nationally notifiable in 2005, 21 human infections with A(H1N1)v, including this one, have been reported to CDC.

Influenza viruses that circulate in swine are called swine influenza viruses when isolated from swine, but are called variant influenza viruses when isolated from humans. There may be important antigenic and genetic differences between seasonal influenza viruses that circulate worldwide in the human population and influenza viruses that normally circulate in swine. Periodic detection of variant influenza viruses is not unexpected given that there is frequent contact between humans and swine and consequently opportunities for virus transmission in both directions.

Swine influenza is a respiratory disease of pigs caused by type A influenza viruses that regularly circulate among swine. Swine influenza A viruses do not usually infect humans, but rare human infections have been reported, usually after exposure to pigs. Since 2005, a total of 467 variant virus infections have been identified in the United States. There has been some limited, non-sustained human-to-human transmission of variant influenza viruses, but no ongoing community transmission has been identified. General information about variant and swine influenza is available at http://www.cdc.gov/flu/swineflu/index.htm.

For more information, see: https://www.cdc.gov/flu/weekly/weeklyarchives2017-2018/Week46.htm.

Animal Disease Events

Summary of Reports: In 2017, the United States submitted six World Organization for Animal Health (OIE) immediate reports for animal disease events. These included two low pathogenic notifiable avian influenza reports, two highly pathogenic avian influenza reports, one atypical bovine spongiform encephalopathy report, and one report for acute hepatopancreatic necrosis disease. In 2017, the United States eradicated New World screwworm in Florida, which was recorded in the U.S. BWC CBM for 2016.

Event summaries can be found, by country and then year of occurrence, on the OIE website: http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home/indexcontent/newlang/en

2017 Immediate OIE reports:

Avian Influenza (Infection with Avian Influenza Viruses)

Avian influenza (AI) is caused by influenza type A viruses, which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free-flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or “H” proteins, of which there are 16 (H1-H16), and neuraminidase or “N” proteins, of which there are 9 (N1-N9). Many different combinations of “H” and “N” proteins are possible. Each combination is considered a different subtype, and each subtype can be further sub-classified as different strains. AI viruses are identified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens. Any influenza A virus (including H5 and H7 avian influenza viruses) in its high pathogenic form is reportable in birds, but only H5 and H7 low pathogenic avian influenza viral infections in poultry are notifiable as per Chapter 10.4 on avian influenza of the OIE Terrestrial Animal Health Code (2017).

Highly Pathogenic Avian Influenza (HPAI), H5N2 Wild Bird—Montana

OIE Immediate Report January 9, 2017—Resolved March 29, 2017

The sample, from a wild mallard duck, was collected on December 27, 2016, as part of the hunter-harvested wild bird avian influenza surveillance program. This detection of HPAI (Eurasian/American) H5N2 virus in a wild bird was not associated with any commercial poultry in the United States.

Highly Pathogenic Avian Influenza (HPAI), H7N9—Tennessee

OIE Immediate Report March 6, 2017—Resolved August 11, 2017

HPAI H7N9 of North American wild bird lineage was identified in a chicken broiler-breeder flock in Tennessee. The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), in conjunction with the Tennessee Department of Agriculture, responded to the event. USDA APHIS and the Tennessee Department of Agriculture conducted a comprehensive epidemiological investigation along with enhanced surveillance and testing. The last positive detection of HPAI H7N9 in poultry was made March 15, 2017. In addition to having no further HPAI detections, the State of Tennessee completed mandatory surveillance in the State and control areas, with negative results for HPAI; depopulated all infected premises, with appropriate disposal; and cleaned and disinfected the infected premises (including, but not limited to, outside areas, equipment, trucks, and other fomites). There were no HPAI detections through wild bird surveillance within 3 months of the closing of the event.

Low Pathogenic Avian Influenza (LPAI), H5N2—Wisconsin

OIE Immediate Report March 6, 2017—Resolved June 23, 2017

Testing of a commercial turkey flock occurred after birds exhibited signs of depression. Samples were submitted for laboratory testing and were confirmed positive for influenza A virus H5N2 LPAI North American wild bird origin. USDA APHIS and the Wisconsin Department of Agriculture, Trade and Consumer Protection conducted and completed a comprehensive epidemiological investigation of this event. In addition to having no further LPAI detections, the following activities were accomplished: completed all mandatory surveillance in officially established control areas with negative results for avian influenza virus; completed the depopulation of the infected premises through controlled marketing of the birds; and finalized the cleaning and disinfection of the infected premises (including, but not limited to, outside areas, equipment, trucks, and other fomites).

Low Pathogenic Avian Influenza (LPAI), H7N9—Alabama, Georgia, Kentucky, Tennessee

OIE Immediate Report March 10, 2017—Resolved June 5, 2017

As part of routine, pre-slaughter testing and surveillance for H5/H7 Avian Influenza, LPAI H7N9 of North American wild bird lineage was detected in healthy broiler-breeder chickens in Tennessee. Subsequent detections then occurred in broiler-breeder flocks in Alabama, Georgia, and Kentucky. The USDA APHIS and State Departments of Agriculture conducted and completed a comprehensive epidemiological investigation of this event. The last positive detection of LPAI H7N9 in poultry was made in March of 2017. In addition to having no further LPAI detections, the following activities were accomplished: completed all mandatory surveillance in the officially established control areas with negative results for LPAI; completed the depopulation of the infected premises and completed the appropriate disposal of birds and material; finalized the cleaning and disinfection of the infected premises (including, but not limited to, outside areas, equipment, trucks, and other fomites); and completed all testing of surveillance samples, all of which tested negative for avian influenza virus.

‘Atypical’ bovine spongiform encephalopathy (BSE)—Alabama

OIE Immediate Report July 18, 2017—Resolved July 19, 2017

BSE is a transmissible spongiform encephalopathy that causes fatal neurological disease of adult cattle. Classical (C-type) BSE occurs when cattle ingest infectious BSE prions from contaminated animal-source proteins. Atypical (H- and L-type) BSE occurs spontaneously. As part of the United States’ targeted surveillance program for BSE, a case of atypical BSE was identified in an 11-year-old beef type cow. This atypical BSE was classified as L-type. Native cases of BSE in the United States have all been atypical BSE cases ─ this is only the fourth case of atypical BSE identified in over 20 years of surveillance. The last case was in 2012. The identified animal did not enter any food supply channels and at no time presented a risk to human health. Specified risk material removal and the ruminant-to-ruminant feed bans continue to be effectively applied.

Acute hepatopancreatic necrosis disease (AHPND)—Texas

OIE Immediate Report August 23, 2017—December 26, 2017

AHPND is caused by the bacteria *Vibrio parahaemolyticus* and causes mass mortality in giant tiger prawns (*Penaeus monodon*) and whiteleg shrimp (*P. vannamei*). AHPND was detected in farmed shrimp (*P. vannamei)* in Texas. The USDA APHIS and Texas Parks and Wildlife Department (TPWD) conducted a comprehensive epidemiological investigation and worked collaboratively to respond to the event. A summary of the epidemiological investigation and response is as follows: the farm was placed under quarantine and all animals were harvested; infected premises (including, but not limited to all harvesting equipment, as well as aerators, pumps, and lined nursery pods) were cleaned and disinfected; all farm ponds and ditches were dried and disinfected; environmental samples and surveillance in the control area were negative for AHPND; and, as a precaution, additional surveillance and requirements prior to restocking will be carried out by TPWD through the Texas Shrimp Inspection Program.

New World Screwworm (*Cochliomyia hominivorax*)—Florida Keys, Florida
OIE Immediate Report October 3, 2016—Resolved March 23, 2017

The New World screwworm fly, Cochliomyia hominivorax (Coquerel) is in the subfamily Chrysomyinae of the dipteran family Calliphoridae (blowflies). New World screwworms are fly larvae (maggots) that can infest livestock and other warm-blooded animals, including people. They most often enter an animal through an open wound and feed on the animal's living flesh. If not treated, infestations can be fatal. While New World screwworm has not been widely present in the United States since the 1960s, it is still found in most of South America and in five Caribbean countries. On October 3, 2016, USDA APHIS announced the confirmation of New World screwworm (*Cochliomyia hominivorax*) in Key deer from the National Key Deer Refuge in Big Pine Key, Florida. New World screwworm had been eradicated from the United States more than three decades ago, and this was the first infestation in Florida in 50 years. USDA partnered with the U.S. Fish and Wildlife Service, Florida Department of Agriculture and Consumer Services, and Florida's Monroe County to prevent the spread of screwworm and to eradicate the screwworm flies from the affected Florida Keys, preserve the endangered Key deer, and protect domestic animals and pets on the Keys. On March 23, 2017, USDA APHIS announced the successful eradication of the New World screwworm from Florida.

Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2018

Department of Health and Human Services (HHS) Open Government Plan http://www.hhs.gov/open/plan	The key principles of Open Government are transparency, collaboration, and participation.
HHS Strategic Plan 2014-2018 http://www.hhs.gov/secretary/about/priorities/priorities.html	The plan describes HHS' work to address complex, multifaceted, and ever-evolving health and human service issues.
National Institutes of Health (NIH) Data Sharing Policy and Implementation Guide http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm	This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy.
Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data http://www.cdc.gov/maso/Policy/ReleasingData.pdf	Public health and scientific advancement are best served when data are shared with public health agencies and academic researchers in an open, timely, and appropriate way.
The Journal *Emerging Infectious Diseases* http://wwwnc.cdc.gov/eid/	Emerging Infectious Diseases is an open access, peer-reviewed journal published by the Centers for Disease Control and Prevention (CDC).
The Morbidity and Mortality Weekly Report (MMWR) http://www.cdc.gov/mmwr/	CDC's primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access.
The Excellence in Science Committee (EISC) at the CDC http://www.cdc.gov/od/science/excellence/	The EISC fosters, supports, and protects an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health.
CDC Office of Science Quality (OSQ) http://www.cdc.gov/od/science/quality/	The OSQ is responsible for increasing the impact of CDC research and science by promoting standards and recommended practices for scientific quality, relevance, credibility, transparency, and utility within the agency and throughout the public health community (e.g., authorship, scientific clearance, peer review, and extramural research policies).
Advancing Excellence and Integrity of CDC Science http://www.cdc.gov/od/science/	The Office of the Associate Director for Science's mission is to strengthen the quality, integrity, and relevance of CDC's science and health impact
Office of Scientific Integrity (OSI) http://www.cdc.gov/od/science/integrity/	OSI ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.
Public Health Image Library (PHIL)	The PHIL offers an organized, electronic gateway

http://phil.cdc.gov/	to CDC images for reference, teaching, presentation, and public health messages; open access.
U.S. Food and Drug Administration (FDA) Publications Database http://www.accessdata.fda.gov/scripts/publications/	An actively updated and searchable research publications database for all FDA publications.
FDA Office of Science and Engineering Laboratories (OSEL) Annual Report https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm	The OSEL Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and research seminars for the fiscal year.
FDA Center for Biologics Evaluation and Research (CBER) http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm	This CBER website provides links to the strategic plan for regulatory science and research, general information about research programs, as well as highlights from selected research publications.
PubMed Central (PMC) http://www.ncbi.nlm.nih.gov/pmc/	PMC is the National Library of Medicine’s digital archive. Final peer-reviewed manuscripts that arise from NIH funds are accessible to the public on PMC no later than twelve months after publication; open access.
The National Institutes of Health (NIH) Public Access Policy http://publicaccess.nih.gov/policy.htm	The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2018

Form E

Relating to	Legislation	Regulations	Other measures[13]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	Yes	No
(b) Exports of micro-organisms[14] and toxins	Yes	Yes	Yes	Yes [1]
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	No	Yes [2]
(d) Biosafety[15] and biosecurity[16]	Yes	Yes	Yes	Yes [3]

EXPLANATORY NOTES

[1] (b) Exports of micro-organisms and toxins:

Amendment of Export Administration Regulations (EAR): Wassenaar Arrangement 2016 Plenary Agreements Implementation - Effective August 15, 2017. This final rule revises the EAR to implement changes made to the Wassenaar Arrangement List of Dual-Use Goods and Technologies at the December 2016 WA Plenary meeting. There are no substantive changes to controls on BWC-related materials or toxins; however, this rule moves the definition of the term 'biological agents' from a Technical Note within Export Control Classification Number (ECCN) 1A004 to the Related Definitions section. See https://www.bis.doc.gov/index.php/forms-documents/regulations-docs/federal-register-notices/federal-register-2017/2074-16904-wa16-rule/file.

[2] (c) Imports of micro-organisms and toxins:

Additional requirements pursuant to existing regulations: On June 5, 2017, following the World Organization for Animal Health's identification of highly pathogenic avian influenza (HPAI) virus in isolates originally reported as low pathogenic avian influenza (LPAI) virus, the U.S. Deparment of Agriculture (USDA) placed additional requirements on the importation of Asian lineage H7N9 avian influenza virus. HPAI virus is a USDA select agent and may only be possessed, used, or transferred in the United States by entities registered with the Federal Select Agent Program (FSAP). In light of continued H7N9 HPAI findings in Asia, FSAP now requires that proposed imports or transfers of Asian lineage H7N9 avian influenza virus undergo additional testing to differentiate between LPAI and HPAI.

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[13] Including guidelines.

[14] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

[15] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

[16] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

[3] (d) Biosafety and biosecurity:

1. Amendments to Select Agent and Toxin Regulations:

- On January 19, 2017, the Departments of Health and Human Services (HHS) and Agriculture (USDA) published parallel amendments to federal regulations for work with select agents and toxins. The regulatory amendments include critical changes to the requirements that must be followed by those working with select agents and toxins, and aim to increase the safety and security of work with these materials. Key components include:
  - Changes to the toxin permissible limits
  - Addition of specific requirements that must be followed for the inactivation of select agents
  - New provisions to the biosafety sections
  - Clarifications to the regulatory language regarding security, training, incident response, and records
  - Clarification that each registered entity must comply with the regulations for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin

  The full texts of these amendments are available at:

  - HHS: Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements (https://www.federalregister.gov/documents/2017/01/19/2017-00726/possession-use-and-transfer-of-select-agents-and-toxins-biennial-review-of-the-list-of-select-agents)
  - USDA: Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations (https://www.federalregister.gov/documents/2017/01/19/2017-00857/agricultural-bioterrorism-protection-act-of-2002-biennial-review-and-republication-of-the-select)

- Regulatory Revision, including Inactivation Guidance and Biosafety Provisions: Effective March 21, 2017, the United States Department of Agriculture (USDA) amended Federal regulations for work with select agents and toxins (82 FR 6197). The regulatory amendments include critical changes to the requirements that must be followed by those working with select agents and toxins, and aim to increase the safety and security of work with these materials. Changes included: revisions to the toxin permissible limits; the addition of specific requirements for the inactivation of select agents; new provisions to the biosafety regulations; clarifications to the regulatory language regarding security, training, incident response, and record management; and clarification that registered entities must comply with the regulations for any select agent or toxin listed on the registration, regardless of whether the entity is in actual possession of the material. Throughout 2017, the Federal Select Agent Program (FSAP), which is coordinated by the United States Department of Health and Human Services (HHS) and USDA, provided a guidance document, regulatory interpretations, and policy statements, related to these amendments, to the regulated community and on the FSAP website. The regulatory amendment/final rule is available at: Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations.

- Addition of *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins: HHS adopted the interim final rule adding *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins, to be regulated as a Tier 1 agent, as final without change. The interim final rule was effective on October 14, 2016. The final rule was published in the Federal Register on April 12, 2017 (https://www.federalregister.gov/documents/2017/04/12/2017-07210/possession-use-and-transfer-of-select-agents-and-toxins-addition-of-bacillus-cereus-biovar-anthracis). In accordance with the interim final rule, any individual or entity that in possession of *B. cereus* Biovar *anthracis* is required to either register in accordance with 42 CFR Part 73 or amend their current registration in accordance with 42 CFR § 73.7(h) and meet all of the requirements of the select agent regulations (42 CFR Part 73).

2. **Select Agent and Toxin Regulations: Policy statements and regulatory interpretations:** Over the course of 2017, the Federal Select Agent Program (FSAP), which is coordinated by HHS and USDA, regulatory interpretations, and policy statements, many related to these amendments, to the regulated community and on the FSAP website. These included:

- Policy statement on the application of the phrases "conclusion of patient care" and "delivery of patient care by health care professionals has concluded" as used in the select agent regulations
- Policy Statement on Access by Restricted Persons
- Policy Statement: Application of the requirement for a "validated inactivation procedure" as used in the select agent regulations
- Policy statement regarding the inactivation of *Bacillus anthracis* and *Bacillus cereus* Biovar *anthracis*
- Regulatory interpretation regarding signature by "Principal Investigator" on inactivation certificates
- Regulatory interpretation regarding surrogate strains which can be used to validate inactivation procedures
- Policy statement for approving transfers to non-possessor entities
- Policy statement regarding the meaning of the phrase "a deviation from a validated inactivation procedure or a viable select agent removal method"
- Regulatory interpretation regarding waste disposal of select agents and toxins
- Policy statement regarding the non-exclusion of study-related activities involving naturally infected animals
- Policy statement regarding the approval of a person to be a Responsible Official at only one entity

3. **Federal Select Agent Program Security and Biosafety Guidance Documents for the Regulated Community:** On May 16, 2017, FSAP posted a new biosafety/biosecurity plan template to assist entities in developing biosafety and biocontainment plans that meet the select agent regulation requirements. FSAP does not require use of the specific template, but provided the customizable template as a resource to ease regulatory compliance. On October 17, 2017, FSAP finalized updates to its Security Plan Guidance to include guidance for the security of Tier 1 agents. Since 2012, Federal regulations require the implementation of additional security measures for Tier 1 select agents and toxins, including pre-access suitability assessments, extra access controls, and extra barriers. The updated document discusses these requirements in detail.

4. Other Measures to Advance Biosafety and Biosecurity in the United States:

- Issuance of Guidance on Principles for Biosafety Governance – Effective October 2017: The Federal Experts Security Advisory Panel (FESAP) has developed a document articulating a number of guiding principles and best practices for biosafety and biosecurity governance. The document *Guiding Principles for Biosafety Governance: Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines* (https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf) also provides an overview of the Federal regulations, requirements, and guidelines that pertain to biosafety and biosecurity in the U.S. and a description of some of the voluntary laboratory accreditation systems. Finally, this document provides a description of the biosafety and biosecurity oversight frameworks that are in place at the institutional level for ensuring compliance with federal requirements and guidelines.

- Research involving potential pandemic pathogens (PPPs) is essential to protecting global health and security. However, there are biosafety and biosecurity risks associated with undertaking such research that should be adequately considered and appropriately mitigated in order to safely realize the potential benefits. The *Department of Health and Human Services (HHS) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf) is intended to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use PPPs resulting from the enhancement of a pathogen's transmissibility or virulence in humans (enhanced PPPs). Enhanced PPP do not include naturally occurring pathogens that are circulating in or have been recovered from nature, regardless of their pandemic potential This new framework describes a robust multidisciplinary, pre-funding review process that considers the potential scientific and public health benefits, biosafety and biosecurity risks, and appropriate risk mitigation strategies to help inform agency decisions. This framework is responsive to, and in accordance with, the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf) issued by the White House Office of Science and Technology Policy on January 9, 2017 and supersedes the previous *Framework for Guiding Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets* (https://www.phe.gov/s3/dualuse/Documents/funding-hpai-h5n1.pdf). Adoption of this framework lifts the research funding pause on HHS research that was set forth by the U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses (https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf)

- Issuance of the Best Practices Checklist for Assessment of Current and Projected Needs for High or Maximum Containment Laboratory Space- Effective December 2017: The Federal Experts Security Advisory Panel has developed a Best Practices Checklist (https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/FESAP-checklist-containment-lab.aspx) to guide Federal departments and agencies through a comprehensive set of questions that should be considered while planning and building a high-containment laboratory. The best practices checklist will help ensure that departments and agencies have considered the different potential options to address their containment research needs and could potentially enable a reduction in the time and cost for planning; design; the release of the request for funding; the award; and the construction of HCL. The checklist should help departments and agencies in operationalizing generalized principles, foster the use of standard methodologies, and assist in developing templates that could be applied to guide assessments of current and projected needs for HCL space, as well as mechanisms to efficiently meet those needs. Other institutions may also use this checklist as a way to ensure that they are aware of all possible elements of biocontainment.

- FBI Security Risk Assessments (SRAs) –3,688 SRAs Completed in 2017: The FBI conducts Security Risk Assessments (SRAs), a requirement of the U.S. Federal Select Agent Program (SAP), on all entities and personnel in the United States requesting possession, use, or transfer of biological select agents and toxins (BSAT). Using various biographical and biometric databases, the FBI determines if a candidate meets the criteria of a "restricted person" based upon a list of prohibitors found under 18 U.S. Code 175b (derived from the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act). In 2017, 3,688 SRAs were processed by the FBI (Criminal Justice Information Services Division, Bioterrorism Risk Assessment Group). Of the 3,688 individual SRAs processed, 17 BSAT access candidates were determined to meet the criteria of a "restricted person." The FBI's adjudication is provided to the Department of Health and Human Services or the Department of Agriculture, who decide whether to grant or deny the requesting entity or individual access to BSAT.
- FBI Biosecurity Outreach: During 2017, the FBI conducted twenty biosecurity outreach events to research institutions across the United States. These outreach events provided an environment where law enforcement and the academic science communities (research students, professors/researchers, biosafety officers, etc.) could engage in mutually beneficial dialogue. During these events, the FBI aimed to: 1) improve situational awareness of biosecurity threats, and 2) foster a mechanism for academia to report suspicious activities. The FBI works to enhance the science community's awareness of threats and vulnerabilities, both internal and external, as scientists can be exploited because of their expertise, access to biological material/technologies, and dual-use potentials. In addition, the FBI conducted several biosecurity outreach events with the amateur biology community in the United States. This outreach includes attendance at amateur biology conferences and regional meetings, FBI-sponsored national workshops, assistance in the development of a safety and security framework, and dissemination of education materials.

Form F

BWC - Confidence Building Measure

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

United States of America

April 15, 2018

Form F

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

1. **Date of entry into force of the Convention for the State party**
   26 March 1975

2. **Past offensive biological research and development programmes:**
   Nothing new to declare

Form G

BWC - Confidence Building Measure

Declaration of Vaccine Production Facilities

United States of America

April 15, 2018

Form G

Declaration of vaccine production facilities

The U.S. Food and Drug Administration publishes a current list of human vaccines licensed in the United States, including associated production facilities. This list is available at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

Data provided on CBM Form G are excerpted from the publicly available website listed above (as accessed on February 3, 2017). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

Form G

Declaration of vaccine production facilities

1. **Name of facility**

Barr Laboratories, Inc.

2. **Location (Mailing Address)**

1235 Mays Mill Road,
Forrest, Virgina 24551

3. **General description of the types of diseases covered:**

Acute respiratory disease caused by Adenovirus Type 4 and Type 7

Vaccines:
- Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

Form G

Declaration of vaccine production facilities

1. Name of facility

Emergent BioDefense Operations Lansing, Inc.

2. Location (Mailing Address)

3500 N. Martin Luther King Jr. Blvd.
Lansing, Michigan 48906

3. General description of the types of diseases covered:

Anthrax disease caused by *Bacillus anthracis*

Vaccines:

- Anthrax Vaccine Adsorbed - [BioThrax]

Form G

Declaration of vaccine production facilities

1. Name of facility

MassBiologics

2. Location (Mailing Address)

University of Massachusetts Medical School
Boston, Massachusetts 02130

3. General description of the types of diseases covered:

Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*.

Vaccines:

- Tetanus and Diphtheria Toxoids Adsorbed

Form G

Declaration of vaccine production facilities

1. **Name of facility**

   Merck Sharp & Dohme Corp.

2. **Location (Mailing Address)**

   PO Box 1000, UG2D-68
   North Wales, Pennsylvania 19454

3. **General description of the types of diseases covered:**

   Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV); Measles; Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

   Vaccines:

   - Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]
   - Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B (Recombinant) Vaccine - [COMVAX]
   - Hepatitis A Vaccine, Inactivated - [VAQTA]
   - Hepatitis B Vaccine (Recombinant) - [Recombivax HB]
   - Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant [Gardasil]
   - Human Papillomavirus 9-valent Vaccine, Recombinant - [GARDASIL 9]
   - Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]
   - Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]
   - Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]
   - Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]
   - Varicella Virus Vaccine Live - [Varivax]
   - Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

Form G

Declaration of vaccine production facilities

1. Name of facility

Organon Teknika Corporation, LLC

2. Location (Mailing Address)

100 Rodolphe Street
Building 1300
Durham, North Carolina 27712

3. General description of the types of diseases covered:

For the prevention of tuberculosis

Vaccines:
- BCG Live [BCG Vaccine]

Form G

Declaration of vaccine production facilities

1. Name of facility

Protein Sciences Corporation

2. Location (Mailing Address)

1000 Research Parkway
Meriden, Connecticut 06450-7159

3. General description of the types of diseases covered:
Disease caused by influenza virus subtypes A and B

Vaccines:
- Influenza vaccine for subtypes A and B [Flublok]

Form G

Declaration of vaccine production facilities

1. Name of facility

Sanofi Pasteur Biologics Co.

2. Location (Mailing Address)

38 Sidney Street
Cambridge, Massachusetts 02139

3. General description of the types of diseases covered:

Smallpox disease

Vaccines:

- Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

Form G

Declaration of vaccine production facilities

1. Name of facility

Sanofi Pasteur, Inc

2. Location (Mailing Address)

Discovery Drive
Swiftwater, Pennsylvania 18370

3. General description of the types of diseases covered:

Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

Vaccines:
- Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]
- Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)
- Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)
- Influenza Virus Vaccine, H5N1
- Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra]
- Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-135]
- Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]
- Tetanus Toxoid for Booster Use Only
- Yellow Fever Vaccine - [YF-VAX®]

Form G

Declaration of vaccine production facilities

1. Name of facility

Wyeth Pharmaceuticals, Inc

2. Location (Mailing Address)

Pfizer, Inc.,
401 N. Middletown Road
Pearl River, New York 10965

3. General description of the types of diseases covered:

Invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F; and invasive disease caused by *Neisseria meningitides* serogroup B.

Vaccines:

- Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]
- Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Appendix A

Biological Select Agents and Toxins

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations. Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: http://www.selectagents.gov.

HHS Select Agents and Toxins

Abrin
Bacillus cereus Biovar *anthracis*
Botulinum neurotoxins
Botulinum neurotoxin-producing species of *Clostridium*
Cercopithecine herpesvirus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
South American Haemorrhagic Fever viruses: Flexal, Machupo, Guanarito, Sabia, Junin
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses: Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever, Russian Spring and Summer encephalitis
Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

OVERLAP Select Agents and Toxins
Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins
African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies mycoides small colony (*Mmm* SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
Synchytrium endobioticum
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix A

NIAID Category A, B, and C Priority Pathogens
The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens is available at: https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category A Priority Pathogens
Bacillus anthracis (anthrax)
Clostridium botulinum toxin (botulism)
Yersinia pestis (plague)
Variola major (smallpox) and other related pox viruses
Francisella tularensis (tularemia)
Viral hemorrhagic fevers
Arenaviruses (LCMV, Junin virus, Machupo virus, Guanarito virus, Lassa virus)
Bunyaviruses (Hantaviruses, Rift Valley Fever virus)
Flaviruses (Dengue virus)
Filoviruses (Ebola, Marburg viruses)

Category B pathogens are the second highest priority organisms/biological agents. They

- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements for diagnostic capacity and enhanced disease surveillance

Category B Priority Pathogens
Burkholderia pseudomallei
Coxiella burnetii (Q fever)
Brucella species (brucellosis)
Burkholderia mallei (glanders)
Chlamydia psittaci (Psittacosis)
Ricin toxin (from *Ricinus communis*)
Epsilon toxin of *Clostridium perfringens*
Staphylococcus enterotoxin B
Typhus fever (*Rickettsia prowazekii*)

Food- and Waterborne Pathogens

- Bacteria: Diarrheagenic *E.coli*, Pathogenic *Vibrio*, *Shigella* species, *Salmonella*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*
- Viruses: Caliciviruses, Hepatitis A virus
- Protozoa: *Cryptosporidium parvum, Cyclospora cayatanensis*, *Giardia lamblia*, *Entamoeba histolytica*, Toxoplasma
- Fungi: Microsporidia

Additional viral encephalitides: West Nile Virus, LaCrosse virus, California encephalitis virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Japanese Encephalitis Virus, Kyasanur Forest Virus

Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of

- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

Category C Priority Pathogens

Emerging infectious disease threats such as Nipah virus and additional hantaviruses
Tickborne hemorrhagic fever viruses (Crimean-Congo Hemorrhagic fever virus)
Tickborne encephalitis viruses
Yellow fever
Tuberculosis, including drug-resistant TB
Influenza
Other Rickettsias
Rabies
Prions
Chikungunya virus
Severe acute respiratory syndrome associated coronavirus (SARS-CoV)
Coccidioides immitis
Coccidioides posadasii
Antimicrobial resistance, excluding research on sexually transmitted organisms[17]

- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations
- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

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[17] NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms: Bacterial vaginosis, Chlamydia trachomatis, Cytomegalovirus, Granuloma inguinale, Hemophilus ducreyi, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, Neisseria gonorrhea, Treponema pallidum, Trichomonas vaginalis

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

Appendix B

Compiled list of microorganisms and toxins used for biodefense research

MICROORGANISM	CATEGORY
African horse sickness virus	USDA Select Agent
African swine fever virus	USDA Select Agent
Avian influenza virus (highly pathogenic)	USDA Select Agent
Bacillus anthracis	Overlap Select Agent + NIAID Category A
Bacillus anthracis (non-viable)	Simulant
Bacillus anthracis Pasteur strain	Overlap Select Agent
Bacillus anthracis Sterne	Simulant
Bacillus anthracis (killed)	Simulant
Brucella abortus	Overlap Select Agent
Brucella melitensis	Overlap Select Agent
Brucella suis	Overlap Select Agent
Burkholderia mallei	Overlap Select Agent
Burkholderia mallei (killed)	Simulant
Burkholderia pseudomallei	Overlap Select Agent
*Burkholderia pseudomallei (*non-viable protein*)*	Simulant
Chapare virus	HHS Select Agent
Classical swine fever virus	USDA Select Agent
Clostridium species producing botulinum neurotoxin	HHS Select Agent + NIAID Category A
Coxiella burnetti	HHS Select Agent
Coxiella burnetti (killed)	Simulant
Crimean-Congo hemorrhagic fever virus	HHS Select Agent
Dengue virus	NIAID Category A
Dengue virus (inactivated)	Simulant
Eastern equine encephalitis virus	HHS Select Agent
Eastern equine encephalitis virus (non-viable protein)	Simulant
Ebola virus	HHS Select Agent + NIAID Category A
Ebola virus (inactivated)	Simulant
Foot-and-mouth disease virus	USDA Select Agent
Francisella philomiragia (inactivated)	Simulant
Francisella tularensis	HHS Select Agent + NIAID Category A
Francisella tularensis (killed)	Simulant
Goatpox virus	USDA Select Agent
Guanarito virus	HHS Select Agent + NIAID Category A
Hantaviruses	NIAID Category A
Hendra virus	Overlap Select Agent
Influenza A virus, reconstructed replication-competent pandemic 1918 strains	HHS Select Agent
Junin virus	HHS Select Agent + NIAID Category A
Kyasanur Forest disease virus	HHS Select Agent
Lassa virus	HHS Select Agent + NIAID Category A
Lujo virus	HHS Select Agent

Lymphocytic choriomeningitis virus	NIAID Category A
Machupo virus	HHS Select Agent + NIAID Category A
Marburg virus	HHS Select Agent + NIAID Category A
Marburg virus (non-viable protein)	Simulant
Monkeypox virus	HHS Select Agent
Mycoplasma mycoides	USDA Select Agent
Newcastle disease virus	USDA Select Agent
Nipah virus	Overlap Select Agent
Peste-des-petits-ruminants virus	USDA Select Agent
Omsk hemorrhagic fever virus	HHS Select Agent
Phoma glycinicola	PPQ Select Agent
Rathayibacter toxicus	PPQ Select Agent
Rickettsia prowazekii	HHS Select Agent
Rift Valley fever virus	Overlap Select Agent + NIAID Category A
Sabia virus	HHS Select Agent
Severe acute respiratory syndrome-related coronavirus	HHS Select Agent
Sheep pox virus	USDA Select Agent
Tick-borne encephalitis complex flavivirus, Far Eastern subtype	HHS Select Agent
Tick-borne encephalitis complex flavivirus, Siberian subtype	HHS Select Agent
Variola major virus	HHS Select Agent + NIAID Category A
Variola minor virus	HHS Select Agent
Venezuelan equine encephalitis virus	Overlap Select Agent
Venezuelan equine encephalitis virus (non-viable protein)	Simulant
Yersinia pestis	HHS Select Agent + NIAID Category A
Yersinia pestis (killed)	Simulant
TOXINS	**CATEGORY**
Abrin	HHS Select Toxin
Alpha conotoxins	HHS Select Toxin
Botulinum neurotoxins	HHS Select Toxin
Diacetoxyscirpenol	HHS Select Toxin
Ricin	HHS Select Toxin
Saxitoxin	HHS Select Toxin
Staphylococcal enterotoxins A, B, C, D, E subtypes	HHS Select Toxin
T-2 toxin	HHS Select Toxin
Tetrodotoxin	HHS Select Toxin